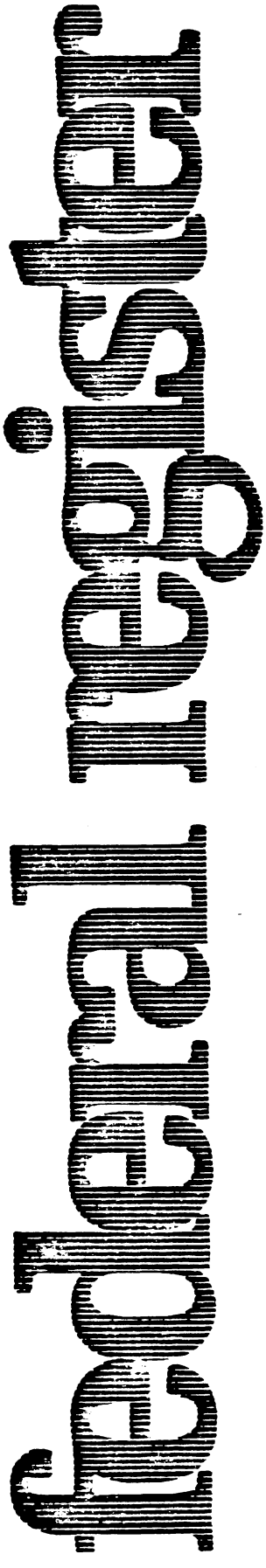

Thursday
August 31, 1989

Part IV

Department of Agriculture

Animal and Plant Health Inspection Service

9 CFR Parts 1, 2, and 3
Animal Welfare; Final Rules

territories, or possessions. This term includes, but is not limited to, animals such as: Deer, skunk, opossum, raccoon, mink, armadillo, coyote, squirrel, fox, wolf.

Wild state means living in its original, natural condition; not domesticated.

Zoo means any park, building, cage, enclosure, or other structure or premise in which a live animal or animals are kept for public exhibition or viewing, regardless of compensation.

Done in Washington, DC, this 25th day of August, 1989.

A. Strating,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 89-20425 Filed 8-30-89; 8:45 am]

BILLING CODE 3410-34-M

DEPARTMENT OF AGRICULTURE

9 CFR Parts 2 and 3

[Docket No. 89-131]

RIN 0579-AA18

Animal Welfare

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the Animal Welfare regulations contained in 9 CFR part 2, to comply with and implement the amendments to the Animal Welfare Act (7 U.S.C. 2131, *et seq.*) ("Act") contained in Pub. L. 99-198, "The Food Security Act of 1985," enacted December 23, 1985, and to reflect our experience in administering the regulations. In addition to rewriting the regulations to facilitate compliance by making them easier to understand, we are adding a new subpart which pertains exclusively to research facilities, and which consolidates all of the regulations in part 2 applicable to research facilities. The revised regulations also provide requirements for registration and licensing under the Act, adequate veterinary care, handling, holding facilities, identification of animals, and recordkeeping. The revised regulations are necessary to clarify the responsibilities of regulated persons under the Act, as amended, and to promote animal welfare.

DATES: This final rule shall become effective October 30, 1989; however, the portions of the rule which concern or relate to information collection and recordkeeping will become effective October 30, 1989, upon approval by the Office of Management and Budget (OMB). The information collection requirements of this final rule have been submitted to OMB for review and approval. The Department has requested that OMB conclude its review no later than October 30, 1989. If any portion is disapproved, notice of disapproval will be published in the **Federal Register** prior to that date.

FOR FURTHER INFORMATION CONTACT: Dr. Dale F. Schwindaman, REAC, APHIS, USDA, Room 206, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-6491.

SUPPLEMENTARY INFORMATION:

Background

This final rule revises the regulations contained in 9 CFR 2.1 through 2.130. It is the result of an intensive effort that began in 1985 when Congress amended the Animal Welfare Act (7 U.S.C. 2131, *et seq.*) (the Act) in Public Law 99-198, "The Food Security Act of 1985," and directed the Secretary of Agriculture to promulgate regulations governing the humane handling, care, treatment, and transportation of animals by dealers, research facilities, and exhibitors, including requirements for exercise of dogs and a physical environment adequate to promote the psychological well-being of nonhuman primates. The final rule reflects APHIS's many years of experience in enforcing the Act and the Animal Welfare regulations. We considered many thousands of public comments in deciding upon the content of the final rule. Our ongoing consultation with the U.S. Department of Health and Human Services, as well as other Federal agencies concerned with animal welfare, also contributed significantly to determining how best to fulfill our statutory mandate.

Due to the length and complexity of this document, it is broken down into general headings and specific subheadings where appropriate, to assist the reader. The supplementary information begins with a brief history of this rule-making. Next we describe the changes we have made in the final rule, both in form and in content. These changes are based upon our reconsideration of the proposed regulations in light of the comments we received and our consultation with other Federal agencies. Part 2 has been reorganized, in part, in this final rule, so that all requirements imposed upon research facilities are contained in one subpart of the regulations. We then discuss, in detail, how the requirements imposed upon research facilities under the final rule differ substantively from the two previous proposals, and how they do not. We also describe other changes we are making to part 2 based upon our reconsideration of those provisions. Our response to the comments we received in response to the March 15, 1989 revised proposal follows. Lastly, we address the concerns raised in the public comment letters and by Federal agencies regarding our economic assessments of the cost of implementing the proposed regulations.

Proposed Rules

The Animal Welfare regulations are contained in Title 9 of the Code of Federal Regulations, chapter I, subchapter A—Animal Welfare, parts 1, 2, and 3 (the regulations). Part 1 provides definitions of the terms used in parts 2 and 3. Part 2 sets forth the administrative and institutional responsibilities of regulated persons under the Act, and part 3 provides specifications for the humane handling, care, treatment, and transportation of animals covered by the Act by regulated entities.

In two documents published in the Federal Register, on March 31, 1987 (52 FR 10292-10298 and 52 FR 10298-10322, respectively), we proposed to revise parts 1 and 2 of the Animal Welfare regulations. In addition to the definitions of terms, the proposed amendments pertained to licensing of dealers and exhibitors, and registration of intermediate handlers, research facilities, and carriers. The proposed regulations also set forth requirements applicable to all regulated entities for recordkeeping and identification of animals, holding periods and facilities, inspections, adequate veterinary care, and requirements for Institutional Animal Care and Use Committees as agents of the research facilities. These changes were proposed under the authority of the Animal Welfare Act, as amended by Congress in 1985. At that time, we did not publish a proposed rule to amend part 3—"Standards" of the regulations.

We solicited comments concerning the proposal for a 60-day period ending June 1, 1987. The comment period was twice extended and ended on August 27, 1987. A total of 7,857 comments were timely received and considered. Many of the comments we received stated that it was difficult to comment upon the proposals to amend parts 1 and 2 of the regulations independently of our proposal to amend the standards in part 3. We have maintained that upon their publication as final rules, parts 1 and 2 of the regulations can be fully implemented with the existing standards in part 3. In response to the comments, we decided to publish revised proposals to amend parts 1 and 2 along with our proposed rule to amend part 3, to assist

the public in reviewing the proposed standards in part 3 and to afford the public an opportunity to comment on the interrelationship of the definitions and regulations in parts 1 and 2 with the proposed standards in part 3. Accordingly, on March 15, 1989, we published in the **Federal Register** three documents: Docket No. 88-013, a proposed rule to amend part 1—"Definition of Terms," (54 FR 10822-10835); Docket No. 88-014, a proposed rule to amend part 2—"Regulations," (54 FR 10835-10897); and Docket No. 87-004, a proposed rule to amend subparts A through D of part 3—"Standards," (54 FR 10897-10954).

The revised proposals published in March, 1989, were prepared with the benefit of the public's comments and reflected our thinking at that time of how best to carry out our statutory mandate and our animal welfare objectives. Throughout this rule-making process, however, we have continued our consideration of alternative means to implement the complex regulatory scheme required by the Animal Welfare Act, as amended, and addressed by the commenters in response to our initial proposal. Many of the comments we received in response to our initial proposal concerned the administrative and economic burdens that the regulations would impose on regulated persons. These concerns were repeated in many comments submitted for our consideration following publication of the March 15, 1989 revised proposal.

We also continued our consultation, in accordance with the requirements of the Act (7 U.S.C. 2145), with the U.S. Department of Health and Human Services (HHS) and members of the Interagency Research Animal Committee (IRAC), a committee comprising representatives of Federal agencies concerned with animal welfare. Together, we evaluated different means of reducing the administrative and recordkeeping burdens the proposed rules imposed upon regulated entities without sacrificing our underlying objectives. The regulatory and economic burdens imposed upon the regulated public in this final rule have been substantially reduced by harmonizing the requirements contained in part 2 for research institutions with those imposed upon the large number of research facilities receiving funding under the Health Research Extension Act of 1985, Public Law 99-158, wherever consistent with our statutory mandate.

We believe this final rule provides a responsible regulatory response to our statutory mandate. It reflects our consideration of the interrelationships between parts 1 and 2 and the standards in part 3 suggested to us in the comments we received. We believe parts 1 and 2 can now be readily implemented while we continue to review the public's comments and consider alternatives concerning the standards that should be included in part 3.

Reorganization of Part 2

The 1985 amendments to the Act affect all regulated entities. However, the most wide-ranging impact is on research facilities. As a result of the amendments, additional institutional responsibilities are imposed on the research community, including: The establishment of institutional animal committees with inspection and reporting duties; providing adequate veterinary care; training of personnel in animal care and treatment; and assurances that animal pain and distress are minimized and that alternatives to painful procedures are considered. Both of our proposals to amend part 2 contained a separate subpart C, applicable only to research facilities, which set forth the duties of the facilities' Institutional Animal Care and Use Committee (IACUC) and many institutional responsibilities. In addition, subpart B set forth the requirements and procedures for research facilities to register under the Act, and subpart D—"Attending Veterinarian and Adequate Veterinary Care," imposed specific requirements on research facilities regarding the provision of veterinary care, which were in addition to the requirements set forth for all licensed or registered entities. Other regulations in the proposed rules contained separate requirements for research facilities as well, such as requirements for identification of animals, recordkeeping, and holding periods.

We have determined that placing all of these requirements in one subpart of the regulations would assist research facilities in understanding their responsibilities under the regulations, and would therefore facilitate their compliance. Accordingly, subpart C is renamed, "Research facilities," in the final rule. It consists of all of the regulations in part 2 that are applicable to research facilities. References to research facilities that were contained in other subparts of part 2 in the revised proposal are removed. Although this results in some duplication in the regulations in cases where an identical provision applies to other regulated entities, we believe it is appropriate to consolidate the many research facility requirements in one discrete subpart to facilitate compliance.

The remaining subparts of part 2 remain substantially as proposed in the revised proposal for the reasons set forth in that document and as discussed below under the general headings, "Other changes to part 2" and "Public comments." Certain sections and paragraphs have been redesignated as a result of the reorganization of research facility requirements.

Subpart C—Research Facilities

Many of the regulations pertaining to research facilities in the revised proposal remain unchanged in the final rule except for their location in the rule and their numerical designation. Others were modified to harmonize them with the guidelines already in place at federally funded institutions, as suggested by many commenters and other Federal agencies. Those facilities comply with the guidelines set forth in the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The modified provisions, as well as those containing more significant departures from the 1987 and 1989 proposals, are discussed below, in the order in which they appear in the final rule.

The following chart provides the derivation of the sections contained in subpart C, paragraph by paragraph, to assist the reader. The sections and paragraphs listed under the heading, "Final rule" were derived either conceptually or specifically from the corresponding sections and paragraphs listed under the heading, "Revised proposed rule."

Derivation Table

Final rule	Revised proposed rule
§ 2.30(a)(1)	§ 2.25(a).
§ 2.30(a)(2)	§ 2.25(b).
§ 2.30(a)(3)	§ 2.25(c).
§ 2.30(b)	§ 2.26.
§ 2.30(c)(1)	§ 2.27(a).
§ 2.30(c)(1)(i)	§ 2.27(b)(1).
§ 2.30(c)(1)(ii)	§ 2.27(b)(2).
§ 2.31(a)	§ 2.35(a)(1), (4).
§ 2.31(b)(1)	§ 2.35(a)(2).
§ 2.31(b)(2)	§ 2.35(a)(3).
§ 2.31(b)(3)(i)	§ 2.35(a)(5)(i).
§ 2.31(b)(3)(ii)	§ 2.35(a)(5)(ii).
§ 2.31(b)(4)	§ 2.35(a)(6).
§ 2.31(c)(1)	
§ 2.31(c)(2)	§ 2.35(b)(1)(i), (ii), (iii).
§ 2.31(c)(3)	§ 2.35(b)(1)(i), (v), (b)(2)(i), (ii)(A).
§ 2.31(c)(4)	§ 2.30(j).
§ 2.31(c)(5)	
§ 2.31(c)(6)	§ 2.35(b)(3).
§ 2.31(c)(7)	
§ 2.31(c)(8)	§ 2.35(b)(3)(i).
§ 2.31(d)(1)	§§ 2.30(a)(4), 2.30(g), 2.35(b)(3)(i).
§ 2.31(d)(1)(i)	§ 2.35(b)(3)(ii)(A).

Final rule	Revised proposed rule
§ 2.31(d)(1)(ii)	§ 2.30(d), (e)(1).
§ 2.31(d)(1)(iii)	§ 2.30(e)(1)(ii).
§ 2.31(d)(1)(iv)(A)	§ 2.30(e)(3), (4).
§ 2.31(d)(1)(iv)(B)	§ 2.30(e)(2).
§ 2.31(d)(1)(iv)(C)	§ 2.30(e)(9).
§ 2.31(d)(1)(v)	
§ 2.31(d)(1)(vi)	§§ 2.30(a)(4), 2.40(c)(3).
§ 2.31(d)(1)(vii)	§§ 2.35(b)(3)(ii)(C), 2.40(d).
§ 2.31(d)(1)(viii)	§ 2.30(e)(6), (8).
§ 2.31(d)(1)(ix)	§§ 2.30(e)(6), 2.35(b)(3)(i), (ii)(C).
§ 2.31(d)(1)(x)	§§ 2.30(f), 2.35(b)(3)(ii)(D).
§ 2.31(d)(1)(x)(A)	§ 2.30(f)(1)(i).
§ 2.31(d)(1)(x)(B)	§ 2.30(f)(1)(iv), (v).
§ 2.31(d)(1)(x)(C)	§ 2.30(f)(1)(vi).
§ 2.31(d)(1)(xi)	§§ 1.1, 2.40(b).
§ 2.31(d)(2)	§ 2.35(b)(3)(i).
§ 2.31(d)(3)	
§ 2.31(d)(4)	§ 2.35(b)(2)(i)(D)(3).
§ 2.31(d)(5)	
§ 2.31(d)(6)	§ 2.35(b)(3)(i).
§ 2.31(d)(7)	
§ 2.31(d)(8)	
§ 2.31(e)(1)	§ 2.31
§ 2.31(e)(2)	§ 2.30(d).
§ 2.31(e)(3)	§ 1.1.
§ 2.31(e)(4)	§ 2.35(b)(3)(ii)(A), (E).
§ 2.31(e)(5)	§ 1.1.
§ 2.32(a)	§ 2.30(i)(1).
§ 2.32(b)	§ 2.30(i)(3).
§ 2.32(c)(1)	§ 2.30(i)(4)(i).
§ 2.32(c)(1)(i)	§ 2.30(i)(4)(v).
§ 2.32(c)(1)(ii)	§ 2.30(i)(4)(vii).
§ 2.32(c)(1)(iii)	§ 2.30(i)(4)(viii).
§ 2.32(c)(1)(iv)	§ 2.30(i)(4)(x).
§ 2.32(c)(2)	§ 2.30(i)(4)(ii).
§ 2.32(c)(3)	§ 2.30(i)(4)(ix).
§ 2.32(c)(4)	§ 2.30(i)(4)(iv).
§ 2.32(c)(5)	§ 2.30(i)(4)(iii).
§ 2.32(c)(5)(i)	§ 2.30(i)(4)(vii).
§ 2.32(c)(5)(ii)	§ 2.30(i)(4)(ii)
§ 2.32(c)(5)(iii)	§ 2.30(e)(1)(ii), (i)(4)(ii).
§ 2.32(c)(5)(iv)	§ 2.30(i)(4)(vi).
§ 2.33(a)	§ 2.40(a).
§ 2.33(a)(1)	§ 2.40(c).
§ 2.33(a)(2)	§§ 2.30, 2.40(e).
§ 2.33(a)(3)	§ 2.40(e)(1).
§ 2.33(b)(1)	§ 2.40(b).
§ 2.33(b)(2)	§ 2.40(c)(3)(iii), (d).
§ 2.33(b)(3)	§ 2.40(d).
§ 2.33(b)(4)	§ 2.40(c)(3)(iii).
§ 2.33(b)(5)	§ 2.40(c)(3)(iii).
§ 2.35(a)(1)	§ 2.35(b)(2)(i), (ii).
§ 2.35(a)(2)	§ 2.30(g).
§ 2.35(a)(3)	§ 2.35(b)(2)(i).
§ 2.35(b)	§ 2.76(a).
§ 2.35(b)(1)–(7)	§ 2.76(a)(1)–(7).
§ 2.35(c)(1)–(3)	§ 2.76(b)(1)–(3).
§ 2.35(d)(1)	§ 2.76(c)(1).
§ 2.35(d)(2)	§ 2.76(c)(2).
§ 2.35(e)	§ 2.76(d).
§ 2.35(f)	§§ 2.30(1), (m), 2.35(b)(2)(i), 2.81.
§ 2.36(a)	§ 2.31(a).
§ 2.36(b)(1)–(8)	§ 2.31(b)(1)–(8).
§ 2.37(a)	§ 2.30(k).
§ 2.38(a)	§ 2.125.
§ 2.38(b)(1)	§ 2.126(a).
§ 2.38(b)(2)	
§ 2.38(b)(3)	§ 2.126(b).
§ 2.38(c)	§ 2.127.
§ 2.38(d)	§ 2.128.
§ 2.38(e)	§ 2.129.
§ 2.38(f)	§ 2.131(a).
§ 2.38(g)(1)	§ 2.50(e)(1).
§ 2.38(g)(2)	§ 2.50(e)(2).
§ 2.38(g)(3)	§ 2.50(d).
§ 2.38(g)(4)	§ 2.51(a).
§ 2.38(g)(5)	§ 2.51(b).
§ 2.38(g)(6)	§§ 2.52(c), 2.53.
§ 2.38(g)(7)	§ 2.52.
§ 2.38(g)(8)	§ 2.54.
§ 2.38(g)(9)	§ 2.55(a).
§ 2.38(g)(10)	§ 2.55(b).
§ 2.38(g)(11)	§ 2.55(c).
§ 2.38(g)(12)	§ 2.55(d).
§ 2.38(h)	§ 2.79(a), (b), (d).
§ 2.38(i)	§ 2.102(b).
§ 2.38(j)	§ 2.101(c).
§ 2.38(k)(1)	§ 2.100.
§ 2.38(k)(2)	§ 2.132(d).
§ 2.38(k)(3)	§ 2.60.

Section 2.30 Registration

Section 2.30 of the final rule sets forth registration requirements and procedures for research facilities. Except for replacement of the term, "Area Veterinarian in Charge," with "APHIS, REAC Sector Supervisor," the registration requirements remain unchanged from the March 1989 proposal. This change reflects an internal agency reorganization within the Animal and Plant Health Inspection Service (APHIS) which created the Regulatory Enforcement and Animal Care organizational unit (REAC). REAC is charged with responsibility for administering and enforcing the Animal Welfare Act and regulations. This term is defined in the final rule to amend part 1—"Definition of Terms," a related document published elsewhere in this issue of the **Federal Register**.

Section 2.31 Institutional Animal Care and Use Committee (IACUC)

As explained in detail in the revised proposal, we received many comments from the research community expressing concern that the Institutional Animal Care and Use Committee (IACUC or Committee) and attending veterinarian were allocated too much responsibility and authority, so that they functioned, in effect, as enforcement agents for APHIS. In response to those comments, we revised the proposed rule by reorganizing the provisions of §§ 2.30 and 2.35 to clarify that the duties performed by the IACUC and the attending veterinarian to ensure compliance with the regulations are ultimately the responsibility of the research facility, and that the research facility must provide them with adequate authority to carry out their functions.

Despite these modifications, it has become evident to us, through our further consideration of the comments received and continued consultation with HHS, that research facilities should be accorded greater flexibility in determining how best to ensure compliance. Research facilities vary greatly in size, in the number of animals they handle, and in the number of personnel they employ. Due to these variations, rigid administrative requirements would be inappropriate for all research facilities, and they should be permitted to develop procedures that satisfy the requirements of the Act and correspond to their operations. We agree that a more flexible approach will achieve the Act's objectives at lower cost to research facilities, many of which already maintain internal review and reporting mechanisms, such as those required under the PHS Policy, than would be incurred under the revised proposal. The mechanisms employed must allow us to inspect for and verify compliance, however, as under the proposed rules. We have therefore modified the provisions regulating the manner in which a research facility, through its Committee, carries out its statutorily assigned duties so that research facilities have the necessary flexibility to develop internal procedures which are best suited for their particular needs. Research facilities are ultimately responsible for complying with the Act and regulations, and must ensure that the procedures they adopt, including those of the Committee, are an effective means of satisfying their obligations.

Changes reflecting greater flexibility, as well as other modifications to the Committee's functions, are explained in detail in this section, in the order in which they appear in the final rule. Due to the redesignation of sections and paragraphs in the final rule, we have included the source paragraph from which the final rule is derived, where appropriate, to assist the reader. The source section number refers to the corresponding provision in our initial proposal or the revised proposed rule of March 1989.

Committee Membership

Section 2.31(a) (revised proposal § 2.30(b)) of the final rule requires that the Chief Executive Officer of the research facility, rather than the "research facility" itself, as required in the proposed rule and revised proposal, appoint an Institutional Animal Care and Use Committee. This change is made to more accurately reflect the statutory language (7 U.S.C. 2143(b)(1)).

We are revising the requirement that the attending veterinarian for the facility be a member of the Committee. Section 2.33(a)(3) of the final rule requires that the attending veterinarian for the facility be a voting member of the Committee, except that facilities that employ more than one Doctor of Veterinary Medicine (DVM) may use another DVM with delegated program responsibility as the

DVM member of the Committee. Accordingly, § 2.31(b)(3)(i) of the final rule (revised proposal § 2.35(a)(5)(i)) is revised to provide that at least one member of the Committee shall be a Doctor of Veterinary Medicine with training or experience in laboratory animal science and medicine. This change continues to fully satisfy the provisions of the Act, as amended (7 U.S.C. 2143(b)(1)(A)), and is consistent with the PHS Policy. It may in fact be preferable at larger institutions where the attending veterinarian's clinical responsibilities are a full-time concern. At many larger institutions, the volume of animal subjects and animal sites under the Committee's purview results in the veterinarian member of the Committee filling an administrative, rather than clinical, role. We believe that a Doctor of Veterinary Medicine, other than the attending veterinarian, can be an appropriate representative for animal care and medical concerns as long as he or she has training or experience in laboratory animal science and medicine.

The final rule does not contain a requirement that the research facility maintain an up-to-date list of Committee members indicating their degrees, position, and qualifications. We had required that this information be maintained by the attending veterinarian and available to us for inspection (revised proposal § 2.35(a)(7)). This information is available to us through a variety of sources and through the Chief Executive Officer of the research facility who is responsible for appointing qualified members to the Committee. Therefore, this recordkeeping requirement can be removed without affecting the ready availability to us of this information.

Committee Functions

The final rule sets forth the functions that the Committee shall perform, "as an agent of the research facility" (final rule § 2.31(c)). We have added this language to allay the commenters' concerns that under the proposed rules, the Committee would operate as an enforcement agent for APHIS. It was never our intent that the Committee carry out APHIS's regulatory responsibilities. Rather, the Committee is intended to function in an oversight and clearing-house capacity to assist the facility in maintaining compliance with the Act and regulations. As stated in the supplementary information accompanying the revised proposal, it is "our intent that institutions act through [the Committee and attending veterinarian] while remaining ultimately responsible." (54 FR 10838)

1. *Semi-annual review and evaluation.* We are retaining the requirement in the final rule for Committee review and evaluation at least once every 6 months of activities involving animals (final rule §§ 2.31(c) (1) and (2)). The revised proposal would require, as part of the inspection of all animal study areas and facilities, that the Committee review "all practices and procedures involving pain to animals" and "the condition of all animals, in order to ensure compliance with the provisions of the Act to minimize pain and distress to the animals." (Revised proposal § 2.35(b)(1)(i) (A) and (B)). We have simplified the final rule by requiring that the Committee inspect all of the research facility's animal facilities, including animal study areas (*see* companion docket 89-130, published elsewhere in this issue of the Federal Register for the definition of "study area"), and that it review the facility's program for humane care and use of animals. The requirement that the Committee use title 9 of the Code of Federal Regulations, chapter I, subchapter A—Animal Welfare, as the basis for its inspection, is continued in the final rule. There is no need to specify that the twice yearly review include a review of painful procedures, since they are necessarily subsumed in the reviews of a facility's program for humane care and use of animals and of all animal facilities and study areas. Specific reference to painful procedures and the condition of animals was based upon the language of the Act and its emphasis on minimizing animal pain and distress (7 U.S.C. 2143(b)(3)). However, as all animal facilities and study areas must be inspected at least once every 6 months under the final rule, we believe this simplification of the regulations accomplishes the same result. In addition, the Committee's review every 6 months of the facility's program for humane care and use of animals will include review of provisions requiring that pain and distress are minimized, and Committee inspection will determine whether the activities are in compliance.

Revised proposal § 2.35(b)(1)(iii) would allow research facilities to apply to the Administrator for an exemption from the twice yearly Committee inspection requirements for animal study areas where the animals are studied in their natural environment and the study area prohibits easy access. Members of the IRAC stated that the requirement to apply for an exemption for field studies would be burdensome, and that as a practical matter, it would be impossible to hold field sites to the same regulatory standards and requirements as dedicated surgical facilities and laboratories.

We agree that it may be impractical and burdensome for research facilities to send their Committees to field sites to conduct inspections and observe subject animals in their natural habitat. In some instances, it may be impossible for the Committee members to observe the condition of the animals if the animals' instincts are to avoid being seen. The Animal Welfare Act, as amended, is primarily intended to promote the humane care and treatment of animals used in biomedical research under captive or laboratory conditions. Subject animals that are studied in their natural habitat would not require the same level of protection as captive animals. We are therefore providing in § 2.31(c)(2) of the final rule that research facilities may determine whether their Committee will inspect animal areas containing free-living wild animals in their natural habitat, and we are deleting the requirement that research facilities apply to the Administrator for an exemption (revised proposal § 2.35(b)(1)(iii)). We are exempting inspection of such areas in the regulations rather than requiring an application for an exemption. However, animals studied at field sites in research activities involving some form of surgical intervention or invasive procedure, or that harm or materially alter their behavior, must be conducted in accordance with the regulations, and the Committee must review any such proposed activity. Field studies, as defined in part 1 of the regulations (*see* companion docket No. 89-130, published elsewhere in this issue of the Federal Register), are exempt from Committee review.

Committee inspection reports must be submitted to the Institutional Official under the final rule (§ 2.31(c)(3)). The revised proposal would require that the Committee also provide a copy of its report to the administrative unit representative (revised proposal § 2.35(b)(2)(ii)(B)). The research facility is responsible for ensuring compliance with the regulations and for correcting deficiencies. For this reason, we are removing the proposed additional requirement in the final rule. The research facility is left to determine what additional administrative reporting steps are necessary for it to ensure compliance, and may include providing a copy of the Committee report to the administrative unit representative as part of its internal procedures.

In response to numerous comments we received following publication of the

March 1987 proposal, we revised the proposed regulations to allow greater flexibility to Committees in performing the requisite twice yearly inspections. The revised proposal would allow subcommittees to perform inspections, as provided under the PHS Policy, however, we added the requirement that all inspections be completed within 30 days of commencing the first inspection.

After further consideration of those comments and further consultation with HHS, we have decided that even greater flexibility is warranted so that the Committee, as an agent of the facility, can determine the best means of conducting and completing the necessary evaluations, based upon the particular circumstances of the research facility. Some institutions maintain dozens or even hundreds of animal study areas and hundreds of animals. At those institutions, Committee responsibilities may require nearly all of the Committee members' time, even though membership on the Committee may be in addition to, and not instead of, their daily work responsibilities.

The Act specifies that semi-annual inspection is one of the principal formal actions required of the Committee. It also specifies that a quorum of the Committee is required for all such formal actions (7 U.S.C. 2143(b)(2)). We believe it is appropriate to allow the Committee to determine its own methodology and timetable for conducting inspections and reviews subject to the requirements of the Act. The Committee must conduct their inspections at least once every 6 months, however, and their reports will be subject to examination by APHIS upon inspection. In this manner, we will be able to determine whether the means selected by the Committee for the conduct of twice yearly evaluations meets the requirements of the statute and the regulations. The research facilities remain ultimately responsible for ensuring compliance with the statute and regulations, and, therefore, must ensure that their Committees are performing their statutory and regulatory duties properly.

In our revised proposal, we sought to satisfy the Act's requirements through the use of subcommittees which would present their findings to a quorum of the Committee for approval. In addition to allowing the IACUC to appoint subcommittees to conduct evaluations, under the terms of the final rule the Committee will also be permitted the option of inviting *ad hoc* consultants to assist in conducting evaluations. Committees may find that using consultants to assist them in fulfilling their responsibilities is beneficial where the consultants have particular knowledge or expertise not otherwise represented on the Committee.

As we noted above, the semi-annual inspection is a vital formal action of the Committee, and the Committee, as an agent for the research facility, is responsible for the conduct of the inspection and the contents of the report as provided in § 2.31(c)(3) of the final rule. A majority of Committee members must review and sign the report, and it must include any minority views. We believe the final rule provides the Committee with additional flexibility to determine the best means of satisfying the statutory requirement. We have modified the reporting requirements in the final rule to allow the Committee to update its report every 6 months (final rule § 2.31(c)(3)). This provision will prove useful for those activities that are ongoing and therefore are repeatedly inspected, and will relieve some of the reporting burden that would be imposed upon the Committee under the revised proposed rule.

The proposed rules would require that the Committee's inspection report contain certain information that is not specifically mandated by the Act. We are revising the reporting requirements in the final rule so that they satisfy both section 13(b)(4) of the Act (7 U.S.C. 2143(b)(4)) and the PHS Policy requirements. Institutions that perform federally funded research under the Health Research Extension Act are already subject to the Committee reporting requirements of the PHS Policy and therefore will not have increased reporting requirements.

The modifications we are making concerning the content of the Committee's report do not affect the substantive elements of the report that are critical for ensuring compliance with the regulations. Section 2.31(c)(3) of the final rule requires that the Committee report describe the nature and extent of the research facility's adherence to the regulations; identify specifically any departure from the regulations and state the reasons for each departure; distinguish significant deficiencies (those that are or may be a threat to the health or safety of the animals) from minor ones, and set forth a reasonable and specific plan and schedule, including dates, for correcting each deficiency. Failure to adhere to the plan and schedule for remedying significant deficiencies shall be reported in writing by the Committee to APHIS and to any Federal funding agency through the research facility's Institutional Official. As under the revised proposal (revised proposal § 2.35(b)(2)(i)(B)), the Committee's report must be signed by a majority of Committee members and must include any minority views of the Committee. We believe the report will be an effective tool for providing information to both the research facilities and to APHIS, and that providing uniformity in reporting requirements for institutions receiving Federal funding will reduce their administrative and reporting requirements.

We are removing the requirement contained in revised proposal § 2.35(b)(2)(i) that the Committee must file its inspection report within 10 business days of completing its inspection of all animal areas. Upon reconsideration of this requirement we have determined that it may not be practical or feasible at large institutions with many animal study areas or at research facilities having more than 3 Committee members, since it may not be possible for those facilities to consolidate all the required information into one report within 10 days. Furthermore, at many institutions the IACUC meets once each month to consider Committee business, and their scheduled meeting may not coincide with a rigid 10-day requirement. In the revised proposal of March 1989, we explained that the 10-day time period was desirable to ensure that inspection information is kept on file and current. The IACUC, as an agent of the facility, is responsible for the evaluation and report; however, research facilities are responsible for ensuring compliance with the Act and the regulations at all times, and for ensuring that the twice yearly evaluations are properly conducted. Accordingly, if upon inspection, we determine that a Committee has not conducted its evaluations and prepared evaluation reports as required by the regulations, we could allege, in an enforcement proceeding, that the research facility is in violation of the regulations. We believe that the provisions contained in the final rule concerning the Committee's reporting requirements will satisfy the statutory objectives and ensure compliance with the Act and regulations.

The proposed requirement for deficiency notification reports and the 30-day correction period are removed from the final rule. We received numerous comments objecting to this requirement, as originally proposed in the March 1987 proposal. Many commenters stated that a fixed 30-day correction period was inappropriate. We revised this requirement in the March

1989 revised proposal to require that notification of a deficiency be reported to the CEO or institutional official, since the research facility is responsible for assuring compliance, within 1 business day of discovery, and to clarify that the 30-day period runs from notification. We also added a 5-day notification period following expiration of the 30-day correction period for notifying APHIS and any Federal funding agency if the deficiency remained uncorrected. Finally, as under the PHS Policy, the revised proposal would allow the Committee to suspend an activity by withdrawing its approval due to noncompliance with an approved activity, formerly referred to as the animal care and use procedure or ACUP.

The rationale underlying the proposed requirements for prompt notification to the facility, the fixed 30-day correction period, and prompt notification to APHIS in the event of noncorrection, was to help ensure timely relief for animals found suffering due to noncompliance with the regulations. We have continued to explore alternative means of assuring that deficiencies are corrected within a reasonable and appropriate timeframe, and have pursued this issue with other Federal agencies concerned with animal welfare. Members of the IRAC were concerned that the 30-day correction period may not be uniformly appropriate for all deficiencies. They stated that the Committee, having observed the deficiency, is in the best position to determine the appropriate amount of time that should be allowed for correcting any deficiency found during an inspection. We agree with the IRAC suggestion and are revising the final rule to provide that the Committee shall set forth in its evaluation report a specific plan and schedule, with dates, for correcting deficiencies. We are maintaining the requirement that uncorrected significant deficiencies must be reported, in writing, to APHIS and funding Federal agencies; however, we are revising the regulations to allow the Committee 15 days to notify the Administrator and any funding Federal agency so that the Committee will have sufficient time to complete the necessary paperwork. We are also maintaining the Committee's authority to suspend an activity for noncompliance. Upon implementation, these provisions will provide an effective mechanism for ensuring that suffering animals are given prompt relief.

Research facilities will continue to be responsible for ensuring that corrective action is taken in a timely manner, in accordance with their responsibility for compliance with the Act and the regulations. Committee reports must be submitted to the Institutional Official under § 2.31(c)(3) of the final rule, and must be maintained by the research facility. They must also be available to APHIS upon request. This will allow us to review the timeframes set by the Committee for correcting deficiencies, and to determine whether they are reasonable and appropriate.

2. *Review and investigation of complaints.* We initially proposed in March 1987, that the Committee must establish a reporting procedure whereby laboratory or research facility personnel or employees could report violations of the Act or regulations, including problems, deviations, or deficiencies in animal care or use. We revised this requirement in § 2.30(j) of the March 1989 revised proposal by placing this responsibility on the research facilities, since they are ultimately responsible for compliance.

We are removing this requirement in the final rule, as explained in greater detail below, and are requiring that research facilities provide training to personnel in methods of reporting deficiencies (7 U.S.C. 2143(d)(4)). The requirement for this training is contained in § 2.32(c)(4) of the final regulations.

We are continuing to require that the Committee, as an agent of the research facility, review, and, if warranted, investigate concerns involving the care and use of animals at the research facility (final rule § 2.31(c)(4); revised proposal § 2.30(j)). We are expanding this requirement, however, to include review, and if warranted, investigation of complaints received from the public, in addition to those received from facility personnel and employees. In amending the Act, Congress acknowledged the importance of public concern for the care and treatment of laboratory animals (7 U.S.C. 2131). We believe that it is important and appropriate that research facilities be responsive to the public, and consider complaints made directly to a facility.

We are removing the requirement that the Committee prepare and file a formal report of these investigations at a central location at the research facility, as required by revised proposal § 2.30(j). The research facility must maintain documentation of the Committees' reviews and investigations conducted in response to complaints received in order to demonstrate its compliance with these regulations, however. In the final rule, the research facility may determine the form and method of such documentation.

3. *Recommendations.* We are adding to the final rule a provision that will require that the Committee make recommendations to the Institutional Offical regarding any aspect of the research facility's animal program, facilities, or personnel training, as part of the Committee's functions (final rule § 2.31(c)(5)). We believe it is appropriate to impose this responsibility upon the Committee, as an agent of the facility, since it conducts first-hand observation of the implementation of the research facility's animal care program. The research facility is responsible for implementing Committee recommendations in order to bring the facility into compliance with the Act and regulations.

4. *Review and approval of proposed activities.* Under the final rule, the Committee is authorized to review and approve, require modifications in, or withhold approval of those components of proposed activities involving animals that are related to the care and use of animals (final rule § 2.31(c)(6)) and significant changes to those activities (final rule § 2.31(c)(7)). These provisions incorporate the prohibition contained in revised proposal § 2.35(b)(3)(i) which states that "[n]o research, testing, or teaching involving warm-blooded animals covered by the Act performed by a facility's personnel at any location shall commence prior to approval of the [animal care and use procedure] of the research, testing, or teaching by the Committee * * *." The language of the final rule reflects that used in the PHS Policy in order to harmonize our mutual requirements, however its substantive import remains unchanged. As explained in greater detail in docket No. 89-130, part 1—"Definition of Terms," the term "activity" is used in the final rule instead of "animal care and use procedure" or "ACUP" to conform the term with that used in the PHS Policy.

Following our initial proposal, we received numerous comments objecting to the requirement for Committee review of animal care and use procedures as exceeding our statutory authority. For the reasons set forth in the supplementary information accompanying the revised proposal (54 FR 10848-10849), we continue to believe that ample statutory authority exists for requiring Committee review of all proposed activities for the care and use of animals, and that such review is necessary in order to fulfill the intent of the Act. Committee review and approval is also required under the PHS Policy for all research facilities receiving funds

under the Health Research Extension Act of 1985. We believe that this requirement should be uniformly applied to all research facilities, as Congress intended.

Our initial proposal of March 1987, would require Committee approval of all painful procedures. As part of the approval process, the Committee would be required to ensure that a proposed activity (referred to as a "protocol" in that document) contained provisions for acceptable and proper animal care, treatment, practices, methods, and use of pain-relieving drugs (initial proposal § 2.35(b)(3)(ii)). Committee approval would be conditioned on the "protocol" containing certain measures and precautions to minimize animal pain and distress unless scientifically necessary and justified in the proposal, and to assure adequate veterinary care. The Committee would be required to obtain written assurances from the principal investigator that alternative procedures were considered and that the experiment was not unnecessarily duplicative (initial proposal § 2.35(b)(3)(iii)–(v)).

The Committee would also be responsible under the initial proposal for the following: (1) Requiring that the principal investigator consult with the attending veterinarian in planning a painful procedure and during it; (2) requiring that the principal investigator provide for the use of pain-relieving drugs in accordance with the attending veterinarian's recommendations; (3) requiring that pre-surgical and post-surgical care be provided in accordance with the attending veterinarian's instructions and veterinary medical and nursing procedures; (4) requiring that all aseptic survival surgeries be performed under aseptic conditions by trained personnel; (5) prohibiting the use of paralytic drugs without anesthesia; and (6) prohibiting the withholding of pain-relieving drugs except when scientifically necessary and approved by the Committee and attending veterinarian. The Committee would have to assure that no animal would be used in more than one major operative experiment from which it was allowed to recover except as provided in the regulations. The Committee would allow exceptions to the Animal Welfare regulations when necessary for accomplishing the research design and explained in detail, in writing, by the principal investigator. (*See* initial proposal § 2.35(b)(3) (vi), (vii) and 2.35(c)).

In the March 1989 revised rule, we stated that many commenters objected that the regulations, as initially proposed, would place too much authority on the Committee and the attending veterinarian. In the supplementary information accompanying the revised proposal, we stated that the statute and the legislative history of the 1985 amendments to the Act supported our initial proposal to impose certain duties and responsibilities on the Committee and the attending veterinarian (54 FR 10845). We also noted our agreement with the commenters that the ultimate responsibility for those duties lies with the research institutions themselves. We revised the proposed rule accordingly, to place responsibility on the research facilities except where specifically reserved to the Committee or attending veterinarian by the Act.

We have continued our consideration of the allocation of authority and responsibilities under the Act. We persist in the view that the research facility is ultimately responsible for assuring that it is in compliance with the Act and regulations. As previously stated in this document, we believe that the Committee, as an agent for the facility, is best situated to carry out many of the research facility's responsibilities under the Act. The research facility must provide the Committee with sufficient authority to carry out the duties delegated to it under the regulations, in order to ensure that it is in compliance.

The final rule is revised to reflect that the Committee, as an agent of the research facility, shall review the animal care and use components of proposed activities to determine that they are in accordance with the regulations unless justification for a departure is presented by the principal investigator in writing (final rule § 2.31(d)). As previously discussed, field studies, as defined in Part 1 of the regulations (*see* companion docket No. 89–130, published elsewhere in this issue of the **Federal Register**) are exempt from Committee review. The requirements that would be imposed upon research facilities under the revised proposal when they engage in potentially painful procedures shall be carried out by the Committee in reviewing all proposed activities involving animals. Accordingly, revised proposal § 2.30(e)(10), requiring that each research facility that engages in any practice or procedure that might reasonably be expected to be a painful procedure establish a written policy to ensure compliance with those requirements, and § 2.30(f), requiring that each research facility establish a written policy which assures that no animal is used in more than one major operative experiment from which it is allowed to recover, are removed.

This modification to the final rule will allow research facilities greater flexibility in carrying out their responsibilities under the Act through their Committee, and will ensure that proposed activities are subjected to close scrutiny, as contemplated by the Act and the proposed regulations. The Committee can develop mechanisms for covering the various elements that must be addressed in conducting their review, however, Committee activities must be reflected in their records in accordance with § 2.35 of the final rule, and available for APHIS inspection. We have conformed the language of the final rule with that of the PHS Policy as it pertains to Committee review of proposed activities involving animals, as part of our effort to harmonize our mutual requirements.

We describe below the requirements that must be satisfied for the Committee to approve a proposed activity or a proposed significant change in an ongoing activity under § 2.31(d) of the final rule.

(a) Procedures involving animals must avoid or minimize discomfort, distress, and pain to the animals (final rule § 2.31(d)(1)(i)). Revised proposal § 2.35(b)(3)(ii)(A) would have required that functional or sensory impairment be minimized, in addition to animal pain and distress in order for the Committee to approve a proposed activity.

The term "discomfort" in the final rule includes a broad range of uncomfortable sensations, including functional or sensory impairment. We consider this modification to be a nonsubstantive conforming change.

(b) Alternatives to procedures that may cause more than momentary or slight pain or distress to the animals must have been considered, and the principal investigator must provide a narrative description, in writing, of the methods and sources that were used to determine that alternatives were not available. This requirement is derived from revised proposal § 2.30(d). In addition, revised proposal § 2.30(e)(1) would have required that the principal investigator provide written assurance to the Committee that alternative procedures were considered and found not suitable, and indicate what information sources were considered.

We have modified the requirement concerning consideration of alternative procedures to allow research facilities greater flexibility in devising internal procedures for their principal investigators to follow, which simplify their task of indicating what sources

were consulted. The principal investigator must provide a written narrative of the sources consulted, such as biological abstracts, Index Medicus, the Current Research Information Service (CRIS), and the Animal Welfare Information Center that is operated by the National Agricultural Library. We believe that in fulfilling this requirement, Committee members will discuss these efforts with the principal investigator in reviewing the proposed activity. We also believe that consideration of alternatives will be discussed during Committee meetings where proposed activities are presented for approval, and made part of the meeting minutes. If the Committee determines that the written narrative prepared by the principal investigator provides adequate assurance that alternatives were considered, the Committee's meeting minutes need only reflect this determination. Committee meeting minutes will be available for APHIS inspection to determine whether alternatives were in fact discussed, and the written narrative of information sources consulted will be made part of the Committee's record. Research facilities will be held responsible if it is subsequently determined that an alternative procedure was available to accomplish the objectives of the proposed experiment. Therefore, the Committee, as an agent of the facility, must satisfy itself that alternatives were adequately considered. We believe that the Act's objectives will be satisfied through this Committee review process.

(c) Similarly, the principal investigator must provide written assurance that the proposed activities do not unnecessarily duplicate previous experiments (final rule § 2.31(d)(1)(iii)). Revised proposal § 2.30(e)(1)(ii) would have required that the written assurance indicate what information sources were consulted, what other procedures were considered, and what techniques will be used to minimize pain and discomfort to animals.

Under the final rule, research facilities are allowed flexibility in devising their own internal procedures for principal investigators to follow in preparing their written assurance. As stated above, we believe that the Committee will explore the efforts underlying the assurance with the principal investigator to determine whether a reasonable good faith effort was made by the principal investigator in determining that a proposed experiment is not unnecessarily duplicative. As is the case in determining whether alternative procedures were available, the Committee, as an agent of the facility, must be satisfied with the assurance. The assurance will be made part of the Committee record in accordance with § 2.35 of the final rule, as will Committee deliberations concerning the proposal, and are therefore available for APHIS inspection. Research facilities will be held responsible if it is subsequently determined that an experiment is unnecessarily duplicative and that a good faith review of available sources would have indicated as much.

(d) If a procedure may cause more than momentary or slight pain or distress to the animals, it must be performed with appropriate pain-relieving drugs, unless withholding of such drugs is justified for scientific reasons, in writing, and continues only for as long as necessary; the attending veterinarian or a designee shall be consulted in planning the proposed activity; and it must not include the use of paralytics without anesthesia.

These provisions are set forth in § 2.31(d)(1)(iv) of the final rule and, except as explained below, are nonsubstantive modifications of the revised proposal (revised proposal §§ 2.30(e) (3), (4); 2.30(e)(2); and 2.30(e)(9); and 2.35(b)(3)(ii)(E)) to conform the language of the final rule with that found in the PHS Policy and to reflect the Committee's review functions under the final rule. The use of appropriate pain-relieving drugs and requirement for consultation with the attending veterinarian will ensure that the drugs are administered in accordance with their accepted and established use. These responsibilities were assigned to the research facility under the revised proposal. As previously explained, we have reassigned these responsibilities to the Committee in the final rule, to carry out as an agent of the facility.

The revised proposal would specifically require that the research facility ensure that the attending veterinarian is allowed access to all animal and research areas at any time during actual research involving a potentially painful procedure (revised proposal § 2.30(e)(2)). This language does not appear in the final rule. The research facility is responsible under § 2.33 of the final rule for ensuring that adequate veterinary care is provided, and that the attending veterinarian has appropriate authority to ensure that adequate veterinary care is provided. This would necessarily require that the attending veterinarian have access to animal study areas in order for the research facility to ensure its responsibilities are satisfied. In addition, the attending veterinarian or his or her delegated representative may be the Doctor of Veterinary Medicine member of the Committee, and would be assured access to all animal study areas in that capacity.

(e) Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure, or during the procedure, if appropriate. This requirement is added to the final rule to reduce animal suffering, pain, and distress.

(f) The living conditions of animals must be appropriate for their species, in accordance with the standards of part 3, and contribute to their health and comfort. The attending veterinarian or other trained, experienced scientist will direct proper housing, feeding, and nonmedical care. The revised proposal would require that the research facility ensure that animals are housed and cared for in accordance with the regulations in 9 CFR, chapter 1, subchapter A (revised proposal § 2.30(a)(4)). It also would require that any deviations from the regulations be fully explained by the principal investigator and approved by the Committee.

We are allowing someone other than the attending veterinarian to direct the housing, feeding, and nonmedical care of the animals as long as that individual has training and experience in the species being maintained or handled. We believe that such an individual is qualified to supervise nonmedical aspects of care. Medical care must be provided as necessary by a qualified veterinarian under final rule § 2.31(d)(1)(vii).

(g) Activities that involve surgery must include appropriate provision for pre-operative and post-operative care of animals in accordance with current established veterinary medical and nursing practices. This requirement modifies revised proposal § 2.30(e)(6) which would require that all pre-procedural, procedural, and post-procedural care be provided by personnel in accordance with the instructions of the attending veterinarian and established veterinary medical and nursing procedures. By not requiring the direct involvement of the attending veterinarian in all matters relating to medical care, research facilities are accorded greater flexibility under the final rule in providing care. However, they are responsible for ensuring that adequate veterinary care is provided. As modified, this requirement satisfies the statutory mandate that a doctor of veterinary medicine be consulted in planning any

procedure that could cause pain to animals and that adequate veterinary care be provided (7 U.S.C. 2143(a)(3) (A) and (C)).

Section 2.31(d)(1)(ix) of the final rule modifies the requirement that would be imposed upon research facilities under revised proposal § 2.30(e)(7) (and upon the Committee, in part, in revised proposal § 2.35(b)(3)(ii)(B)) that survival surgeries be conducted only in facilities intended for that purpose, under aseptic conditions using aseptic techniques. Under the final rule, the requirement for a dedicated surgical area applies to major operative procedures conducted on animals other than rodents, however all survival surgery or operative procedures must be done under aseptic conditions using aseptic procedures. There is no statutory requirement that procedures be performed in dedicated surgical areas. However, we believe it is advisable to require such areas when surgical procedures are performed on larger animals to reduce the risk of infection. Surgeries performed on rodents typically require limited, contained work space, and therefore can be performed in non-dedicated areas using aseptic procedures and techniques. Requiring that surgical procedures performed on rodents be done under aseptic conditions, and that adequate veterinary care be provided, should be sufficient to protect those rodents that are covered by the Act from infections due to surgery. In addition, dedicated facilities are not required at field sites, however, all operative procedures must be performed under aseptic conditions using aseptic procedures.

(h) Personnel who conduct procedures on the species being maintained or studied must be appropriately qualified and trained in those procedures. This language modifies the requirements of revised proposal §§ 2.30(e)(6) and 2.30(e)(8). Under § 2.32 of the final rule, research facilities are responsible for ensuring that personnel are appropriately qualified. Section 2.33 requires that the facility's program of adequate veterinary care include pre- and post-procedural care in accordance with current established veterinary medical and nursing procedures. This change is intended to allow research facilities greater flexibility in accomplishing the same objective.

(i) No animal can be used in more than one major operative procedure from which it is allowed to recover unless justified, such as when required by or related to other surgical procedures, in writing, by the principal investigator, required as a routine veterinary procedure or to protect the health or well-being of the animal as determined by the attending veterinarian; or in other special circumstances as determined by the Administrator upon request. This requirement and the exceptions to it were contained in revised proposal §§ 2.30(f)(1) and 2.35(b)(3)(ii)(D), except that reference to endangered species or marine mammals and the provision that cost savings is not adequate justification for multiple use of animals are removed. Such concerns may be addressed to the Administrator as an element of the special circumstances which might justify multiple major operative procedures.

(j) The method of euthanasia that will be used in a proposed activity must be consistent with the definition set forth in part 1 of the regulations (*see* docket No. 89–130, published elsewhere in this issue of the **Federal Register**), unless a deviation is justified for scientific reasons, in writing, by the principal investigator. This provision is added to the final rule in order to ensure that only humane methods of euthanasia are utilized.

The revised proposal would have provided that the research facility require that the attending veterinarian provide training of personnel in the proper use of pain-relieving drugs in order to minimize pain and distress to animals (revised proposal § 2.30(e)(5)). This requirement does not appear in the final rule. However, we believe our objective is satisfied by requiring that the Committee, in reviewing a proposed activity, determine that appropriate pain-relieving drugs will be used unless scientifically justified in writing (final rule § 2.31(d)(1)(iv)) and that the personnel who will be conducting procedures on the animals are appropriately qualified and trained in those procedures (final rule § 2.31(d)(1)(x)).

As set forth above, § 2.31(d)(1) of the final rule continues, in modified form, the provision of revised proposal § 2.30(g) that exceptions to compliance with the regulations and standards contained in title 9 CFR, chapter I, subchapter A—Animal Welfare may be made by the research facility when necessary to accomplish the research design, specified in the proposal for the activity, explained in detail, and approved by the Committee. Under the final rule, the Committee as an agent of the facility, has responsibility for determining that a proposed activity is in accordance with 9 CFR, chapter I, subchapter A, unless an acceptable justification is presented. As under the revised proposal, the research facility must maintain, as part of its recordkeeping responsibilities under § 2.35 of the final rule, records of proposed activities. These records will therefore contain the written justification presented by the principal investigator for any departure from the regulations, and, in accordance with the final rule, must be available to APHIS inspectors. This will enable us to determine whether the facility is in compliance with this provision of the regulations and is allowing departures from the regulations only when properly justified and documented.

We are removing the requirement that a copy of all written reports detailing and explaining exceptions to the regulations be attached to the research facility's annual report. During our consultation with members of the IRAC, objections were raised to attaching copies of written reports to the annual report on the grounds that it is unduly burdensome and not required by the Act. Section 13(a)(7) of the Act requires that research facilities provide assurance to the Secretary that the facility is adhering to the standards and provide an explanation for any deviation. We proposed that a copy of the detailed report be attached to a research facility's annual report, in addition to being made available at the facility to APHIS inspectors, to assist us in determining whether a facility is in compliance with the Act and the regulations. It would also assist us in preparing our comprehensive annual report to Congress, as required under section 25 of the Act (7 U.S.C. 2155).

Upon reflection, we believe the IRAC comment has merit. Copies of the written reports are not necessary to fulfill the statutory requirement. Therefore, we are requiring in the annual report an assurance that the facility is adhering to the standards and regulations under the Act, and that it has required that exceptions be specified and explained by the principal investigator and approved by the Committee. We believe that requiring this assurance and inspecting Committee records at the research facility will reduce the paperwork and administrative burden that would be imposed upon those facilities under the revised proposal, and still fulfill the statutory directive of the Act. A summary of all written detailed reports of departures from the regulations, including a brief explanation of the departure and identification of the species and number of animals affected by the exception must be attached to the annual report (7 U.S.C. 2143(a)(7)(B)(iii)).

It must also include the numbers of animals used in painful procedures for which pain-relieving drugs were not used and an explanation for withholding the drugs. This information is necessary to enable us to determine whether a facility is in compliance with the regulations, to prepare our report to Congress, and to determine whether closer scrutiny of an approved exception or the Committee approval process itself is warranted. Requirements for the research facility's annual report are contained in § 2.36 of the final rule.

Our initial proposal of March 1987 would have required Committee approval of a proposed "protocol" that would cause more than short-term minor pain or distress before the procedure could commence. As explained in ample detail in the supplementary information accompanying the March 1989 revised proposal, we eliminated the proposed categories of animal use and determined that requiring Committee review and approval of all animal care and use procedures, consistent with the PHS Policy, was preferable. (*See* 54 FR 10865–10866). In further response to the comments we received, we revised the mechanism for accomplishing Committee review in order to relieve the heavy burden that would be imposed upon the Committee, by incorporating the PHS Policy approach of assigning ACUPs to individual Committee members for review and recommendation, unless a member requests in depth review by a quorum of the Committee. The revised proposal would require that the Committee member's recommendations be presented to the Committee for formal action by a quorum of its members, under authority of section 13(b)(2) of the Act (7 U.S.C. 2143(b)(2)).

During our consultation with members of the IRAC, concern was expressed that assembling a quorum of the Committee would delay or impede research, and in cases where immediate action would be required, such as a proposal to harvest vital organs from euthanized animals, would be impractical. It would also place a huge burden on Committee members at research facilities that conduct a great many activities, since Committee members would be responsible for official action on large numbers of proposals.

We have decided to retain the provisions of the revised proposal which allow proposed activities to be assigned to individual Committee members for review in order to allow greater flexibility in carrying out the Committee's review and approval responsibilities. Under the final rule, however, the reviewing member(s) of the Committee will also be authorized to approve or require modifications to proposed activities in order to secure approval. The reviewing member of the Committee may also request full Committee review. In addition, as under revised proposal § 2.35(b)(3)(i), any member of the Committee may request full Committee review of a proposal.

Our purpose in requiring Committee review of proposed activities involving animals, as stated in the supplementary information accompanying our initial proposal, is to ensure "that all possible steps have been taken to reduce or eliminate as much pain and distress as possible, and that the proper level of animal care and treatment has been planned for and carried out using acceptable practices and methods." (52 FR 10302). We believe that the final rule, as further revised, accomplishes this objective with less burden on Committee members.

Section 2.31(d)(2) of the final rule requires that each Committee member receive a list of proposed activities before they are reviewed, and that written descriptions of proposed activities involving animal care and use be available to all members for their consideration. As stated above, any member of the Committee can request full Committee review. In this manner, all of the Committee members participate in determining whether an individual member of the Committee may be authorized, as an agent of the Committee, to approve a proposed activity. If any Committee member determines that more in depth scrutiny of a proposed activity is necessary, approval may be granted only after review at a convened meeting of a quorum of the Committee. As an additional precaution, the final rule precludes the participation in the approval process of any member who has a conflicting interest in the proposed activity.

As with inspections, the final rule provides for the participation of invited consultants in reviewing proposed activities. Since publication of our initial proposal in March 1987, we have continued to consider the most effective means of carrying out Committee reviews so that they accomplish our stated objective, as set forth above. We can foresee instances where the Committee, composed of a minimum of 3 members, 1 of whom is not affiliated with the research facility and is intended to represent community interests, may not possess the requisite expertise to evaluate all of the complex issues presented by a proposal or to understand its implications for the animals' health and well-being. By allowing research facilities, through their Committees, to invite consultants to participate in the review process, we are providing research facilities with the authority they require to conduct meaningful reviews and thereby ensure the proper care, treatment, and use of animals.

Section 2.31(d)(4) provides the mechanism by which the Committee notifies the principal investigator and the research facility, in writing, of its decision to approve, withhold approval, or require modification of a proposed activity. Our proposals did not prescribe requirements for notification, although the research facility would be responsible if it allowed unapproved activities to proceed. We are supplementing our proposals by requiring written notification of the Committee's disposition of each proposed activity involving the care and use of animals. If the Committee determines to withhold approval, it must provide the principal investigator and the research facility with a written statement explaining its decision. The principal investigator then has the opportunity to respond to the Committee, either in person or in writing. On the basis of the response, the Committee may reconsider its decision.

Section 2.35(b)(1)(iv) of the revised proposal added a mechanism, in accordance with the PHS Policy, for the Committee to suspend or withdraw its approval of an activity involving pain to animals if the Committee determines upon inspection that the practice or procedure is not being conducted in accordance with the approved animal care and use procedure (ACUP) or the regulations. As explained in the supplementary information accompanying the revised proposal, withdrawal of approval means that the procedure or practice must cease, or the research facility will be considered to be in violation of the regulations (54 FR 10866). Accordingly, the revised proposal provided that the Committee must direct the CEO or institutional official to instruct the principal investigator to cease all noncomplying activities immediately.

Upon further consideration of this provision, we have determined that additional clarification of the Committee's role and the institution's responsibilities in this regard is necessary. The final rule is revised to clarify that the Committee may suspend an activity after a convened quorum of

the Committee has reviewed the matter and a majority of the quorum favors suspension. Suspending an activity that is in progress may require that the principal investigator discontinue an experiment and start the project over from the very beginning. This may be an exceedingly costly consequence, in terms of time and funds, and may require that the animals involved be destroyed or replaced. We believe that before such drastic action is taken, a quorum of the Committee should be presented with this decision. If immediate action is necessary, the Committee member who discovered the deficiency may request an emergency meeting. Under the final rule, the Committee, as agent of the research facility, rather than the CEO or Institutional Official, is authorized to direct cessation of noncomplying activities. In order to provide the Committee with this authority, which was previously reserved to the head of the facility, it is necessary in accordance with section 13(b)(2) of the Act to require a quorum of the Committee (7 U.S.C. 2143(b)(2)).

As under the revised proposal, we are requiring that the Institutional Official be apprised that by virtue of the suspended activity the facility had not been operating in compliance with the regulations. The Institutional Official must review the reasons for the suspension with the Committee and take appropriate corrective action in order to bring the facility back into compliance. The Institutional Official must report the corrective action taken to APHIS, and to any funding Federal agency (final rule § 2.31(d)(7)). This requirement carries out the directive of section 13(b)(4)(A)(ii) of the Act which requires that the Committee include, as part of its inspection report, any deficient conditions and any deviations of research practices from originally approved proposals that adversely affect animal welfare, any notification to the facility regarding such conditions, and any corrections made thereafter (7 U.S.C. 2143(b)(4)(A)(ii)), and does so in a manner that is consistent with the PHS Policy. This practice is therefore already in place at many research institutions.

In addition, we are adding a provision to allow officials of the research facility to further review activities approved by the Committee and significant changes to approved activities that are ongoing. Research facilities are ultimately responsible for ensuring compliance with the Act and regulations and are therefore responsible for the proper functioning of their Committees. Section 2.31(d)(8) of the final rule, consistent with the PHS Policy, specifically provides that Institutional Officials at research facilities may review Committee activities and determinations, however, they may not override or circumvent the Committee's decision on a proposed activity, including a decision on suspension.

We are adding a provision to the final rule to require that the Committee conduct continuing review of activities covered by the Animal Welfare regulations at appropriate intervals, and at least annually (final rule § 2.31(d)(5)). This review is in addition to the twice yearly evaluations required by final rule § 2.31(c) and is intended to provide current information to the research facility regarding all ongoing activities so that it can remain in compliance. Follow-up reviews of problematic conditions discovered during evaluations must be conducted, as determined necessary by the Committee.

Section 2.31(e) of the final rule identifies the information that must be provided by the principal investigator to the Committee as part of his or her proposal to conduct an activity involving animals. The revised proposal did not specifically list the information that must be provided to the Committee, however, it did specify the aspects of animal care and use the Committee must consider in evaluating a proposed care and use procedure. In order to perform its evaluation completely and properly, the Committee would need to consider this information. In order to provide guidance to principal investigators in the preparation of proposals and thereby facilitate implementation of the rule, we have identified in final rule § 2.31(e) the information that must, at a minimum, be included in a proposal submitted to the Committee.

Personnel Qualifications and Training

Section 2.30(i) of the revised proposal would require that each research facility provide for the training and continuing education of personnel involved with animal use, care, and treatment, and that the training be reviewed by the Committee and the attending veterinarian. It would also require that training be made available annually or as appropriate to individuals and their responsibilities, and that research facilities review the status of the training and qualifications of researchers who use animals at least once each year.

Although the Act places responsibility for training upon the research facility (7 U.S.C. 2143(d)), in considering the comments we received and in preparing the revised proposal, we determined that this responsibility could best be carried out through the attending veterinarian because of his or her expertise, and through Committee review (*See* 54 FR 10854–10855).

Based upon our ongoing consultation with HHS and members of the IRAC, as well as our continuing consideration of the comments we received, we have revised the final rule to place responsibility for training on the research facilities, and to let them determine the best means of satisfying their statutory obligations. Accordingly, § 2.32(a) of the final rule provides that it shall be the responsibility of the research facility to ensure that its personnel involved in animal care, use, and treatment are qualified to perform their duties, and that partial fulfillment of this responsibility shall be through providing training and instruction to those personnel.

The revised proposal would require that research facilities maintain a written policy ensuring that all personnel qualifications are reviewed annually. The review could be done separately or as part of another personnel review. The latter requirement was added in the revised proposal in response to the numerous comments we received objecting that a separate, annual review would be costly and impractical. It was also based upon our consultation with HHS, during which it was pointed out that many facilities have internal mechanisms for reviewing personnel qualifications and performance.

In the course of our further consultation with HHS and members of the IRAC following publication of the revised proposal, we recognized that because many, if not most, research activities last far longer than one year, it is more important that research facilities establish at the outset of the activity that the personnel involved in the care, use, and treatment of animals are properly qualified and trained to assure their humane care and treatment, and that the requirement of annual review would be unnecessary and burdensome in many instances. We are therefore revising the final rule to clarify that research facilities are responsible for ensuring that their personnel are properly trained and qualified. Accordingly, § 2.32(b) of the final rule requires that training and instruction be made available, and the qualifications of personnel reviewed, with sufficient frequency to fulfill the research facility's responsibilities to ensure its personnel are qualified and that it is in compliance with the regulations. Under this provision, facilities may establish their own internal means and procedures for

assessing the training and qualifications of their personnel, as long as they ensure that their statutory responsibilities are satisfied. The requirement that research facilities maintain a written policy ensuring annual review of personnel is removed.

We have also removed the requirement that training be available for review by APHIS inspectors. Rather than looking at prepared training materials in order to determine whether personnel are qualified to perform their duties and are complying with the regulations, APHIS inspectors will be better able to assess and evaluate the qualifications of laboratory personnel by observing their performance in the course of APHIS inspections, and by determining, through observation and review of Committee records, that personnel are properly carrying out approved activities and are in compliance with the regulations.

We are continuing to require training in the areas listed in the revised proposal § 2.30(i)(4), except that we have removed the reference in paragraph (i)(4)(xi) to requiring other training, techniques, or procedures as the research facility or the Secretary may feel is necessary. The research facility has the authority to require additional training under § 2.32(a) of the final rule. If we identify other areas of training that should be included in the regulations, we will publish a document in the Federal Register proposing to do so. We are removing the requirement for training in the common or accepted use of pain-relieving drugs in those species for which the drug is not licensed, in order to conform our regulations with the requirements of the Food, Drug, and Cosmetic Act. Finally, we have made minor modifications in the description of the areas in which we require training, to conform our language more closely with that used in the PHS Policy. We consider these changes to be nonsubstantive.

We are removing reference to an established reporting procedure whereby laboratory or research facility employees can report violations of the Act or regulations. The final rule requires training in methods for reporting deficiencies in animal care and treatment. As part of this training, research institutions may choose to establish formal procedures for reporting violations, and we encourage them to do so. However, we do not believe it is necessary to prescribe such a procedure in the regulations.

Attending Veterinarian and Adequate Veterinary Care

We initially proposed in March 1987, that research facilities, as well as other regulated entities, establish and maintain written programs of adequate veterinary care and provide a copy annually to APHIS for our review (initial proposal § 2.40). The requirement that research facilities provide adequate veterinary care is statutorily mandated. Section 13(a)(2) of the Act directs the Secretary to promulgate standards to govern the humane handling, care, treatment, and transportation of animals, including minimum requirements for adequate veterinary care (7 U.S.C. 2143(a)(2)(A)). Section 13(a)(3)(A) further requires that adequate veterinary care include the appropriate use of pain-relieving drugs in painful procedures or euthanasia (7 U.S.C. 2143(a)(3)(A)).

Our objective in requiring a program of adequate veterinary care was to ensure that research facilities attend to the health needs of animals, including disease control and prevention, pest and parasite control, pre- and post-procedural care, nutrition, euthanasia, and the appropriate use of pain-relieving drugs. Our objective in requiring that a written program be maintained was to provide a means of verifying that all aspects of veterinary care were covered by the facility's program, and to ensure upon inspection that research facilities were operating in compliance with their program requirements. We did not prescribe more precise requirements for addressing the areas that should be included in such a program, because, as we stated in the supplementary information accompanying the revised proposal, "[i]t is the responsibility of the dealer, exhibitor, or research facility to ensure that its program of veterinary care adequately covers those areas." (54 FR 10868)

In response to the March 1987 proposal, we received many comments critical of our requirement for a written program of veterinary care at facilities with full-time or staff attending veterinarians. As explained in the supplementary information accompanying the revised proposal, HHS suggested to us in the course of our consultation following publication of the 1987 proposal, that because institutions having a full-time attending veterinarian on staff would maintain written standard operating procedures covering their program of veterinary care, they should not be required to maintain a separate written program. They felt that this requirement would unnecessarily burden research facilities by requiring duplication of effort with no additional benefit to animal welfare. We agreed with their position in the March 1989 revised proposal, and modified our proposed requirements to provide that the written program could be incorporated within the facility's standard operating procedure or other document. APHIS inspectors could then examine it on the premises, rather than requiring a separate submission.

Upon further consideration of the proposed requirements, we have determined that research institutions that employ a full-time attending veterinarian to administer the facility's program of adequate veterinary care, need not present to us a written program of veterinary care. They must maintain a program of adequate veterinary care, however, and are responsible for ensuring that adequate veterinary care is provided to the animals. The research facility must accordingly provide the attending veterinarian with appropriate authority to carry out the facility's program of veterinary care. The program of adequate veterinary care must include having appropriate facilities, personnel, equipment, and services to comply with the Animal Welfare regulations; apppropriate methods to prevent, control, diagnose, and treat diseases and injuries, including emergency and weekend care; daily observation of all animals to assess their health and well-being; guidance by the attending veterinarian to personnel in animal care and use techniques, including the use of pain-relieving drugs and euthanasia; and adequate pre-procedural and post-procedural care. Upon inspection, APHIS inspectors will evaluate the appearance and condition of the animals as well as the facility, to determine whether the veterinary care program is adequate to ensure that proper care is being rendered, and whether the facility is in compliance with its program. Accordingly, we believe the revised language of § 2.33 in the final rule will achieve our objective of ensuring that proper veterinary care is provided to all animals.

Part-time attending veterinarians would be less likely to have the degree of oversight over compliance with the facility's program of adequate veterinary care that full-time attending veterinarians enjoy. For this reason, and for the reasons set forth in the supplementary information accompanying the March 1989 revised proposal, research facilities, as well as other regulated entities, that utilize an attending veterinarian on a part-time or consultant basis, are required to maintain a written program of adequate

veterinary care under the final rule. They must employ the attending veterinarian under formal, that is, contractual arrangements, that include regularly scheduled visits to the facility, to ensure that the program is properly implemented on an ongoing basis. The written program of adequate veterinary care should include such things as the facility's name and address; the attending veterinarian's name and address; provision for the different areas of care identified above as necessary for an adequate program of veterinary care; the system or method of euthanasia that will be employed and the personnel authorized to perform it; and the dated signature of the attending veterinarian and the Institutional Official. This document must be maintained by the facility and made available to APHIS inspectors in accordance with § 2.38(b) of the final rule.

We have modified the requirement for daily observation of animals to provide that someone other than the attending veterinarian may carry it out, provided that the research facility maintains a means of direct and frequent communication to the attending veterinarian so that care can be promptly provided. Such care should also include the humane disposal of sick, diseased, injured, lame, or blind animals, as would be required under revised proposal § 2.40(d), unless doing so is inconsistent with research purposes.

As explained under the subheading, "Committee membership," under the final rule, the attending veterinarian is not required to be a member of the Committee at those facilities employing more than one Doctor of Veterinary Medicine. A DVM with delegated program responsibility may also serve on the Committee, in accordance with the Act (7 U.S.C. 2143(b)(1)(A)).

Recordkeeping Requirements

Section 2.35 of the final rule consolidates the various recordkeeping requirements imposed upon research facilities in the revised proposal. Paragraph (a) requires that research facilities maintain Committee records, including minutes of Committee meetings, records of attendance, records of any Committee activities and deliberations, records of proposed activities involving animals and proposed significant changes in those activities, the Committee's disposition of the proposed activity, and the Committee's reports of reviews and evaluations prepared in accordance with § 2.31(c)(3) of the final rule. Any actions taken by a Committee member or subcommittee in carrying out their duties under this part must be recorded in writing and maintained by the research facility as a Committee record. This includes reviews and evaluations as required under § 2.31(c), reviews of proposed activities as required under § 2.31(d), and any action taken regarding an activity involving animals under § 2.31(d).

As under the revised proposal, research facilities are responsible for maintaining all such records, and must do so for at least 3 years (final rule § 2.35(f)). We have added a requirement that records that relate to an approved activity be maintained for the duration of the activity plus an additional 3 years after completion of the activity (final rule § 2.35(f)). This requirement replaces the provisions of revised proposal § 2.81, as they relate to research facilities, which would prohibit research facilities from destroying or disposing of records for a period of 1 year without the written consent of the Administrator, and require that facilities maintain records pertaining to an animal for at least 1 year after the animal is euthanized. All records and reports must be available for inspection and copying by authorized APHIS or funding Federal agency representatives as under revised proposal § 2.35(b)(2)(i), and must be retained pending completion of an investigation or proceeding under the Act.

The remaining requirements for recordkeeping set forth in § 2.35 of the final rule are taken directly from § 2.78 of the revised proposal without change for the reasons set forth in the supplementary information accompanying the initial proposal and the March 1989 revised proposal.

Annual Report

The requirements imposed upon research facilities in completing and submitting their annual report are set forth in § 2.36 of the final rule. We have made conforming changes to reflect changes in terminology from the revised proposal. The requirements remain substantially as proposed in the March 1989 revised proposal, except as indicated and explained below.

We are revising the requirement that an explanation detailing and explaining any deviation from the standards and regulations be attached to the annual report (revised proposal §§ 2.30(g) and 2.31(b)(3)) and the requirement that a detailed statement on the procedures producing pain or distress and explaining the reasons pain-relieving drugs were not used be attached to the annual report (revised proposal § 2.31(b)(7)). The Act requires that each research facility report annually that the provisions of the Act are being followed and that professionally acceptable standards are being followed during research or experimentation (7 U.S.C. 2143(a)(7)(A)). Section 13(a)(7)(B)(iii) of the Act further requires that research facilities provide, as part of their report, "an explanation for any deviation from the standards promulgated under this section." (7 U.S.C. 2143(a)(7)(B)(iii)). Upon reconsideration of our proposal, we have determined that requiring a summary and explanation of all exceptions to the regulations which indicates the number of animals, by species, that were affected by those exceptions, and requiring an explanation for the withholding of pain-relieving drugs in any painful procedure, will be sufficient to fulfill the requirements of the Act. If, based upon our review of the summaries attached to a facility's annual report, we determine that additional information is required in order to assess whether the facility is in compliance with the Act and regulations, we may request further documentation and detail. For this reason, and as explained above, under the heading, "Committee functions," we have revised the annual reporting requirements in the final rule to require a summary and brief explanation of all exceptions to the regulations, rather than a more detailed explanation.

We are removing the statement that would be required by the Chief Executive Officer or institutional official under revised proposal § 2.31(b)(9) regarding the authority of the Committee and the attending veterinarian to enter any animal or research area at any reasonable time in order to carry out their responsibilities, and that the facility complies with the Act, regulations, and standards. We received numerous comments in response to this requirement as proposed in our initial proposal of March 1987, objecting to it as redundant and unnecessary. In the supplementary information accompanying the revised proposal, we noted our general concurrence with the commenters' argument, however we felt an additional statement from the institutional official was warranted. Upon reconsideration, we agree with the commenters that the additional assurance does not provide any greater assurance of compliance, and that it may be removed. The research facility is responsible under the regulations for ensuring that the Committee and the attending veterinarian have sufficient authority to carry out their duties, therefore an assurance to that effect is subsumed in the assurances required under § 2.36(b)(1) that professionally

acceptable standards governing the care, treatment, and use of animals were followed, and under § 2.36(b)(3) that the facility is adhering to the standards and regulations under the Act. Accordingly, this additional assurance is removed in the final rule.

We are also removing the provision set forth in the revised proposal which would require that the institutional official certify that each member of the Committee was given an opportunity to express concurrence or nonconcurrence with the report and to attach a minority report. This provision is not mandated by the Act. In the supplementary information accompanying the revised proposal, we stated that we felt it was important that all members of the Committee be afforded an opportunity to express a minority or nonconcurring view to the Department (54 FR 10860–10861). We are removing this provision from the final rule because section 13(b)(4)(A)(iii) of the Act and § 2.31(c)(3) of the final rule expressly provide a mechanism for Committee members to express minority views and it is therefore unnecessary to require additional minority opinions in the annual report. All minority views of Committee members must be included in the Committee's twice yearly evaluation reports and made available to APHIS inspectors upon inspection.

Miscellaneous

1. *Access and inspection of records and property.* We received many comments from the research community objecting to the provisions of proposed § 2.126 which would require research facilities, as well as other regulated entities, to permit APHIS representatives to enter facilities during business hours for inspection purposes and to take photographs to document their findings. As explained in the supplementary information accompanying the revised proposal, there is ample statutory authority for this provision (54 FR 10877). We believe it is essential for enforcement purposes that APHIS have access to research facilities at all reasonable times. Accordingly, we have made no substantive change in our regulations in this regard. However, we are mindful that, in amending the Act, Congress did not authorize the Secretary to interrupt the conduct of actual research or experimentation during inspections (7 U.S.C. 2143(a)(6)(A)(iii), and APHIS inspections will be conducted in accordance with the statutory requirements.

2. *Inspection for missing animals.* We are removing the provision in the revised proposal which would allow research facilities to limit access of law enforcement officers searching for missing animals to those not undergoing actual research or experimentation. We believe the proposed limitation on the authority of law enforcement officers would be inappropriate.

3. *Confiscation and destruction of animals.* We are making one change in the regulations concerning confiscation and destruction of animals held by research facilities. Under the revised proposal, APHIS officials would have authority to attempt to notify the research facility that an animal is found suffering and that the situation must be corrected or the animal euthanized, when the animal "is no longer required" to carry out the research, test, or experiment for which it was utilized (revised proposal § 2.129(a)). Section 2.38(e)(1) of the final rule broadens this authority by including animals that are not in actual use. Under the final rule, an APHIS official can require that the situation be corrected or may confiscate an animal when he or she finds that it is suffering due to noncompliance with the regulations, even if the animal is being held for future use. We believe that this provision is necessary as a means of minimizing animal suffering resulting from a facility's failure to comply with the regulations.

4. *Handling.* The revised proposal continued the prohibition set forth in the initial proposal of March 1987 against food or water deprivation as a means of training, working, or handling animals (revised proposal § 2.131). This provision prompted comments from the research community stating that it was unnecessarily restrictive and would interfere with research. HHS suggested that such practices be addressed by the principal investigator and reviewed by the Committee. As explained in the supplementary information accompanying the revised proposal, we decided to retain the prohibition to prevent inhumane practices (54 FR 10879). During our ongoing consultation with HHS and members of the IRAC, members of the IRAC stated that short-term food or water deprivation has become an accepted practice in incentive-reward training systems utilized by the research community, as well as exhibitors, and that if done in accordance with reasonable and customary professional practices, is not inhumane. Rather, they stated that short-term deprivation more closely approximates animals' natural feeding patterns in the wild, where they must hunt or forage for food.

We agree that certain short-term food or water deprivation may be an effective and humane method of handling animals, however, it must be conducted with the approval of the research facility's Committee and monitored by the facility to ensure that it is reasonable and in accordance with professional practices.

Section 2.38(f)(2)(ii) of the final rule provides that short-term withholding of food or water is allowed when specified in a proposed activity and approved by the Committee. The animal care and use procedure specified in the proposal must include a description of the monitoring procedures that will be employed, to ensure the animal's welfare and compliance with the approved proposal. We believe that with these safeguards, short-term withholding of food or water will not endanger the animals or be inhumane.

5. *Compliance with standards.* We are revising the provision requiring compliance by research facilities with the regulations unless an exception to compliance has been specified and justified in the proposal to conduct an activity involving animals, and approved by the Committee. Section 2.100(a) of our initial proposal addressed the requirement for compliance by research facilities with the standards in part 3. We revised paragraph (a) in the March 1989 revised proposal by including § 2.131. Handling, in addition to the standards in part 3. This change was necessary because the regulations for handling are currently contained in part 3. Our proposals to amend part 2 have included uniform provisions for handling all the animals covered by the Act. Part 3 will now be amended by removing the separate provisions for handling found in the different subparts.

In the final rule, we have revised this provision by adding that exceptions to the regulations in subpart C—"Research Facilities," may also be made only when specified and justified in the proposal and approved by the Committee. This change merely restates § 2.31(d)(1) which requires that the animal care and use components of a proposed activity be in accordance with the Animal Welfare regulations unless acceptable justification for a departure is presented and approved by the Committee. We therefore consider this to be a nonsubstantive change.

Other Changes to Part 2

Section 2.27 Notification of Change of Operation

We are revising § 2.27(b) by removing the requirement that a registrant file an annual report. This change clarifies that registrants other than research facilities

are not required to submit annual reports.

Section 2.40 Attending Veterinarian and Adequate Veterinary Care

We are revising the requirements applicable to dealers and exhibitors concerning their attending veterinarian and program of adequate veterinary care. We are doing so for reasons similar to those explained under the heading, "Subpart C—Research Facilities, Attending Veterinarian and Adequate Veterinary Care." We initially proposed in March 1987, that dealers and exhibitors, in addition to research facilities, maintain written programs of adequate veterinary care and provide a copy annually to APHIS for our review. Dealers and exhibitors must comply with standards which require that they provide adequate veterinary care, in accordance with the Act (7 U.S.C. 2143(a)(2)(A)). We did not prescribe detailed program requirements for providing such care, other than that the program of veterinary care include disease control and prevention, pest and parasite control, pre- and post-procedural care, nutrition, and euthanasia, because, as we stated in the supplementary information accompanying the revised proposal, "[i]t is the responsibility of the dealer, exhibitor, or research facility to ensure that its program of veterinary care adequately covers those areas." (54 FR 10868).

In response to our initial proposal, we received numerous comments objecting to the regulations concerning the written program of adequate veterinary care, and stating that they would not be appropriate for entities having a full-time attending veterinarian on staff. We agreed with the commenters in part, and in the revised proposal modified the regulations to provide that dealers, exhibitors, and research facilities having a full-time attending veterinarian need only have a written program of veterinary care available for APHIS inspection on the premises. The written program could be included in another document.

We have reconsidered those comments and have revised the final rule to require that dealers and exhibitors employ, under formal arrangements, an attending veterinarian who shall provide adequate veterinary care. If the attending veterinarian is a full-time employee, the program of veterinary care need not be written. As stated above, it is the responsibility of the dealer or exhibitor to ensure that adequate veterinary care is provided. If, upon inspection, we determine from the appearance and condition of the animals and premises that adequate veterinary care is not being provided, we will find the dealer or exhibitor in violation of the Act and the regulations.

If a dealer or exhibitor employs a part-time or consultant attending veterinarian, the final rule requires that the formal arrangements include a written program of adequate veterinary care and regularly scheduled visits to the dealer or exhibitor (final rule § 2.40(a)(1)). This is because part-time attending veterinarians would be less likely to maintain the degree of oversight over the provision of veterinary care that full-time attending veterinarians enjoy. Employees of the dealer or exhibitor would require the guidance of a written program, and dealers and exhibitors must ensure that their personnel comply with the program.

The written program of adequate veterinary care should include such things as the facility's name and address; the attending veterinarian's name and address; provision for the different areas of care identified in the regulations; the system or method of euthanasia that will be employed and the personnel authorized to perform it; and the dated signature of the attending veterinarian and a responsible official of the dealer or exhibitor.

As under the requirements applicable to research facilities, we are modifying the requirement for daily observation of animals to provide that someone other than the attending veterinarian may carry out the requirement as long as a mechanism of direct and frequent communication is in place to keep the attending veterinarian informed. The final rule also specifically requires the availability of emergency, weekend, and holiday care.

Because we are consolidating the requirements to provide veterinary care to all regulated animals in this section, we are removing the requirements for providing veterinary care set forth in 9 CFR part 3 of the regulations.

Section 2.131 Handling

We are revising the handling regulations to allow exhibitors to withhold food or water on a short-term basis only. As explained above under the heading "Subpart C—Research Facilities, Miscellaneous," short-term food or water deprivation has become an accepted practice in incentive-reward training systems used by exhibitors. We proposed to prohibit any such deprivation because of our concern that such methods of training can be cruel and inhumane. We agree with members of the IRAC, however, that if done in accordance with reasonable and customary professional practices, they are not inhumane. They may, in fact, more nearly approximate the animals' feeding patterns in nature. In order to ensure that deprivation is done on a short-term basis only, we are requiring that each animal receive by the end of each day, its normal daily intake of food and nutrition requirements, and that it is sufficient to meet the animals' dietary requirements.

Sections 3.111 and 3.135 of part 3—"Standards," subparts E and F provide handling requirements for marine mammals and warmblooded animals other than dogs, cats, rabbits, hamsters, guinea pigs, and nonhuman primates respectively. Section 3.135 was included as part of part 3, subpart F, which was added when Congress amended the Act in 1970 to include all warmblooded animals used for research or exhibition purposes, or sold as pets. Section 3.111 was added in 1979 when standards covering marine mammals were added to part 3. Subparts A through D do not contain comparable provisions. As stated in the supplementary information accompanying the proposed rule for part 2, published March 31, 1987, 52 FR 10306, our experience has demonstrated the necessity for handling regulations to protect the welfare of all animals covered by the Act, and to enable the Department to better prosecute cases of inhumane handling and treatment. Accordingly, § 2.131 of the final rule provides handling regulations applicable to all animals covered by the Act. Sections 3.111 and 3.135 are removed from part 3.

Public Comments

The revised proposal published March 15, 1989, solicited comments on the narrow issue of the interrelationship of the definitions and regulations in parts 1 and 2 of 9 CFR, chapter I, subchapter A, with the standards we proposed in part 3. As explained in that document, we did so to allow the public an opportunity to comment on parts 1 and 2 where they are inextricably intertwined with part 3, since the proposed standards had not been presented for public comment in March 1987, and to give the public the benefit of our most current thinking on how to implement the 1985 amendments to the Act in preparing their comments on the proposed standards. This continuation of the rule-making process enabled us to consider further the comments we received in response to our initial proposal, to look at additional regulatory alternatives, and to continue our consultation with the U.S. Department of Health and Human

Services and other Federal agencies interested in animal welfare, and to do so in light of the comments submitted on the interrelationship of the different parts of the regulations.

We solicited comments on the narrow interrelationship issue for a 60-day period, ending May 15, 1989. Comments that were postmarked or received by that date were considered in preparing this final rule. We solicited comments on the standards of part 3 for a 120-day period, ending July 13, 1989. Comments that were not timely for consideration in preparing final rules for parts 1 and 2 will be considered if they address the proposed standards or the regulations in general.

Five thousand five hundred eighty-two comments were timely received for consideration in preparing final rules for parts 1 and 2. Many comments concerned the Animal Welfare regulations generally or conceptually. We considered those comments in preparing this document since they address the Department's regulatory approach as a unit, and thereby implicate the interrelationship of parts 1, 2, and 3. Many comments went beyond the issue of the interrelationship of the three parts and duplicated previously stated concerns that the regulations, as proposed, would impose unnecessary additional administrative burdens upon research facilities and did not allow research facilities to utilize their existing internal procedures and lines of authority to accomplish our objectives. The comments also objected that many of the proposed recordkeeping and reporting requirements imposed upon regulated entities would be time consuming, costly, and unduly burdensome, without any corresponding benefit to animal welfare. Comments submitted by the research community continued to address the responsibilities and authority that would be imposed upon the Institutional Animal Care and Use Committee and the attending veterinarian under the revised proposal. These points were raised in response to our initial proposal of March 1987, and have had a profound and continuing impact on the development of alternative regulatory approaches. As such, they have been integrated into this final rule.

We address below the comments we received in response to the revised proposal of March 1989 concerning the interrelationship of parts 1, 2, and 3. Comments on the proposed definitions of terms as they apply to parts 2 and 3 are addressed in companion docket No. 89-130, published elsewhere in this issue of the **Federal Register**. Comments on the regulatory impact analysis and the regulatory flexibility analysis prepared by the Department in accordance with Executive Order 12291 and the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), respectively, are addressed separately at the conclusion of this supplementary information.

General Comments on the Interrelationship of the Regulations

We received 303 comments (293 from members of the general public, 9 from the research or scientific community, and 1 from a dealer) expressing general support for the revised proposal, although one commenter from the general public stated that subpart C—"Research Facilities" was poorly organized and redundant. Subpart C has been revised in the final rule to include all requirements applicable to research facilities. We describe those changes under the heading, "Subpart C—Research Facilities," elsewhere in this document. Twenty-six commenters (19 members of the general public, 5 members of the research or scientific community, and 2 dealers) supported an increased budget for animal welfare matters. Three hundred fourteen commenters (41 members of the general public, 244 members of the research or scientific community, and 29 dealers) expressed general opposition to more stringent regulations, and one dealer commented that the budget should be reduced.

We believe these final regulations carry out the mandate of Congress, as expressed in the 1985 amendments to the Animal Welfare Act, that regulated persons be required to establish and maintain internal procedures that ensure the humane care and use of animals, and that they demonstrate their compliance with the Act to the Department.

Six hundred sixty commenters (652 members of the general public and 8 members of the research or scientific community) urged that the revised proposed rules be published as final regulations no later than June 15, 1989. In a civil action filed by the Animal Legal Defense Fund against the Department, the Office of Management and Budget, and the U.S. Department of Health and Human Services, seeking the publication of final regulations on parts 1 and 2 without further delay, we represented to the court that USDA would make the necessary changes in parts 1 and 2 of the regulations in consideration of the public comments and in consultation with interested Federal agencies within 30 days following the close of the comment period. As promptly as practicable, USDA would submit the final rules to the **Federal Register** for publication. The enormous task of reviewing the large volume of comments we received in response to the March 1989 revised proposal, and the task of completing our consultation with HHS and other Federal agencies, have prevented us from publishing final rules on parts 1 and 2 by June 15, 1989.

In order to accommodate this timetable, and to achieve our objective of publishing final rules on parts 1 and 2 without further delay, we declined to extend the 60-day comment period, as some commenters requested. We received 614 comments (72 from members of the general public, 537 from members of the research or scientific community, 3 from exhibitors, and 2 from dealers) requesting that we reopen parts 1 and 2 for substantive comments. The primary impact of the changes made in the revised proposal was to reallocate responsibility for certain duties and obligations under the Act from the Committee and attending veterinarian at research facilities to the facility itself. These changes were made in response to the nearly 8,000 comments we received following the March 1987 proposal. We solicited additional comments on the issue of the interrelationship of the various parts of the regulations only, and did so in response to the comments we received following the March 1987 proposal. The additional changes we are making in this final rule reflect our further consideration of those comments as well as the comments we received on the interrelationship of the regulations. This final rule presents the Agency's response to the more than 13,000 comments we have received. We believe that final rules may now be promulgated without further delay.

Forty-two commenters (24 members of the general public, 17 members of the research or scientific community, and 1 dealer) wrote to express their opposition to the use of any animals in research. By way of contrast, 21 commenters (10 members of the general public and 11 members of the research or scientific community) wrote to express their support for the unrestricted use of animals in biomedical research, and 385 commenters (100 members of the general public, 283 members of the research or scientific community, and 2 dealers) expressed support for the responsible and caring use of animals in research when no scientifically valid alternative to animal use exists. We also received 739 comments (504 from members of the general public, 232 from members of the research of scientific community, and 3

from dealers) supporting provisions intended to reduce the suffering of laboratory animals. One member of the general public stated that laboratory animals should be relieved from any pain whatsoever.

In amending the Animal Welfare Act, Congress explicitly acknowledged that "the use of animals is instrumental in certain research and education for advancing knowledge of cures and treatment for diseases and injuries which afflict both humans and animals; * * *" (7 U.S.C. 2131). At the same time, however, Congress determined that alternative testing methods that do not require animals are being developed that are faster, less expensive, and more accurate, and that eliminating or minimizing unnecessary duplication of experiments on animals can result in more productive use of Federal funds (7 U.S.C. 2151). In response to public concern for laboratory animal care and treatment, the 1985 amendments to the Act imposed restrictions on the use of animals so that pain and distress will be minimized whenever possible, alternatives to painful procedures will be considered and unnecessary duplication of experiments avoided, withholding of pain-relieving drugs will be limited to when scientifically justified, and adequate veterinary care will be provided. The 1985 amendments also prohibit using an animal in more than one major operative experiment unless necessary for scientific purposes or under other special circumstances (7 U.S.C. 2143(a)). These final regulations reflect the determination of Congress that while biomedical research using animals is necessary, regulations to ensure that such research is conducted responsibly and humanely are also necessary.

We received 984 comments (159 from members of the general public, 823 from members of the research or scientific community, and 2 from dealers) objecting that the revised proposal exceeds the statutory authority provided by the Act, and that it does not comport with the Congressional intent underlying the 1985 amendments. Five members of the research or scientific community stated that the regulations as proposed go beyond ensuring the humane care and use of laboratory animals.

The March 1989 revised proposal points out, in precise detail, APHIS's statutory authority for the proposed regulatory amendments. It does so in response to the comments we received to the March 1987 proposal objecting that APHIS lacked statutory authority for many of the proposed changes. The revised proposal also demonstrated that the legislative history supports those changes. In this final rule, we have included specific references to our statutory authority, as we did in the supplementary information accompanying the revised proposal, to demonstrate that ample statutory authority for these final rules exists.

We received 476 comments (132 from members of the general public, 342 from members of the research or scientific community, and 2 from dealers) stating that the revised proposal consists of rigid engineering standards rather than performance standards, contrary to the directives of Executive Order 12498, which requires adherence to the policy guidelines established by the Presidential Task Force on Regulatory Relief. The Task Force expressed preference for performance-based or result-oriented regulatory standards, rather than precise engineering requirements, because the latter are generally considered cost-ineffective, especially when uniformly applied on a nationwide basis.

The regulations made final in this rule reflect our further consideration of the concerns raised by the commenters, and those expressed by other Federal agencies in the course of our consultation with them. Through the process of ongoing consultation with HHS and members of the IRAC, we explored additional regulatory alternatives that would allow regulated entities to develop internal procedures that accomplish our regulatory objectives. The flexibility allowed regulated persons under this final rule should allay the commenters' concern that we are imposing unnecessarily rigid engineering requirements at unwarranted expense. The final rule for part 2 imposes responsibility upon research facilities for ensuring compliance with the regulations and standards promulgated under the Animal Welfare Act. We will inspect these facilities and examine their records and reports to determine that they are fulfilling this responsibility.

Two hundred eighty commenters (74 members of the general public, 204 members of the research or scientific community, and 2 dealers) argued that the legislative history of the 1985 amendments to the Act indicates that APHIS's authority is limited to promulgating regulations that are consistent with the guidelines contained in the PHS Policy, issued by HHS pursuant to the Health Research Extension Act of 1985, and was not intended to result in significant cost increases for regulated entities. That Act directs the Secretary of HHS, through the Director of the National Institutes of Health (NIH), to establish guidelines for the proper care and treatment of animals used in biomedical and behavioral research, including the establishment of animal care committees. Those guidelines are contained in the PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy). Two hundred thirty-seven commenters (66 members of the general public, 169 members of the research or scientific community, and 2 dealers) further suggested that if HHS and APHIS remain unable to agree on the nature and scope of our statutory authority the Attorney General should be requested to resolve the dispute in accordance with Executive Order 12146.

Three hundred fifty commenters (75 members of the general public, 273 members of the research or scientific community, and 2 dealers) protested that the revised proposal would radically alter established PHS and NIH policies, and were not supported by scientific evidence to justify doing so. Five hundred eleven commenters (132 members of the general public, 377 members of the research or scientific community, and 2 dealers) recommended that we adopt the PHS Policy to reduce duplication and avoid inconsistency between the regulations and the Policy. Ten members of the research or scientific community urged that we reconsider allowing research facilities to comply with either the Animal Welfare regulations, the PHS Policy, Food and Drug Administration regulations, or the American Association for the Accreditation of Laboratory Animal Care (AAALAC) accreditation standards. We received 365 comments (85 from members of the general public, 278 from members of the research or scientific community, and 2 from dealers) objecting that we did not coordinate with the Secretary of HHS in issuing the revised proposal. Two hundred sixty-three commenters (70 members of the general public, 191 members of the research or scientific community, and 2 dealers) further suggested that APHIS does not have the technical competence to promulgate these rules.

The Animal Welfare Act was passed by Congress in 1966, long before the Health Research Extension Act of 1985 and the PHS Policy existed. The Act has been amended several times, most recently in 1985, to reflect public concern over the care and treatment of animals used in research, and maintained or handled by dealers, exhibitors, carriers, and intermediate

handlers. Section 15(a) of the Act requires that the Secretary of Agriculture consult and cooperate with other Federal agencies in establishing standards, and consult with the Secretary of HHS before issuing regulations (7 U.S.C. 2145(a)). We have continued the consultation described in the supplementary information accompanying the revised proposal (54 FR 10837), in an effort to coordinate our requirements wherever it is consistent with our statutory mandate to do so. We believe that this final rule resolves all of the issues raised by HHS in response to our proposals to amend parts 1 and 2 of the regulations, and that it serves our mutual objectives of animal welfare.

Notwithstanding our desire to resolve our outstanding differences with HHS, we are mindful that Congress has entrusted the Department with responsibility for establishing minimum requirements to carry out its mandate, and for administering the Act because of our expertise in animal welfare matters. We are accountable to Congress and the public for doing so. By harmonizing our regulations with the HHS guidelines wherever doing so is consistent with the Act, we have developed final rules that allow those research facilities receiving funds under the Health Research Extension Act of 1985 to utilize their existing internal procedures where they satisfy the requirements of the Act. The modifications made in the final rule will also allow other research facilities greater flexibility in developing internal procedures which ensure that the objectives of the Act are satisfied. Modifications to the requirements imposed upon research facilities in the final rule are explained in detail under the heading, "subpart C—Research Facilities." Any outstanding differences remaining between the PHS Policy and these final rules are necessary to fulfill our statutory obligations, as directed by Congress.

We are not adopting the regulations of the Food and Drug Administration or the accreditation standards of AAALAC. Congress has mandated that we promulgate regulations implementing the Animal Welfare Act, and that we provide minimum standards for the humane care and use of laboratory animals. Standards or requirements promulgated by other agencies or associations do not accomplish our objective of ensuring compliance with certain minimum requirements. The PHS Policy and the AAALAC accreditation standards are guidelines for facilities that are either Federally funded or that desire accreditation status, respectively. We do not have the authority to enforce them. Furthermore, the 1985 amendments require specific minimum standards, such as exercise for dogs and psychological well-being of nonhuman primates, that have no counterpart in the regulations of other agencies. We believe it is desirable to administer and enforce one uniform body of regulations at all research facilities regulated by the Act. We considered the regulations and guidelines of other agencies and research associations in developing our earlier proposals and these final rules, and have attempted to harmonize our mutual requirements wherever it was consistent with our mandate to do so.

Three hundred thirty commenters (66 members of the general public, 262 members of the research or scientific community, and 2 dealers) repeated the comment that APHIS has failed to show a rational connection between the proposed rules and the Agency record. As we stated in the supplementary information accompanying the revised proposal, we have been charged with the responsibility of administering and enforcing the Animal Welfare Act, and implementing regulations, since the Act was enacted in 1966. The proposed amendments to the regulations and the regulations promulgated in this final rule reflect our many years of experience in implementing the Act. We have determined where additional regulatory requirements are needed to ensure the safeguards intended by the Act are provided and to promote animal welfare. We believe that, upon implementation, these final rules will assist us in enforcing the Act and in preventing circumvention of its requirements.

We received 396 comments (100 from members of the general public, 294 from members of the research or scientific community, and 2 from dealers) stating that we did not respond fully in the revised proposal to the comments submitted in response to the March 1987 proposal, and that we did not provide sufficient reasons for declining to make changes suggested by the commenters. We disagree. Many months were devoted to reviewing the nearly 8,000 comment letters received. All of the comments were carefully considered, and many changes were made as a result of those comments. The rationale underlying our decisions to revise the proposed regulations, or not to revise them to include suggested changes, is explained in great detail in nearly 60 **Federal Register** pages, in the supplementary information accompanying the revised proposals for parts 1 and 2 (see 54 FR 10822–10832 and 54 FR 10835–10882)

Two commenters (1 dealer and 1 exhibitor) stated that the revised proposal is written in a manner that makes it difficult to understand and to comment upon. One of our stated objectives in revising the regulations is to make them easier to understand, thereby increasing compliance and making them more effective. We believe that we have accomplished this objective in the final rules for parts 1 and 2. If, upon implementation of the regulations, we determine that further clarification is necessary, we will provide it in a document published in the **Federal Register**. No further changes are made in the final rule based upon this comment.

We received a number of different comments objecting to the regulations on the grounds that they will impede research in various ways. We received 643 comments (104 from members of the general public, 534 from members of the research or scientific community, and 2 from dealers) objecting that the regulations in the revised proposal would unduly burden research with excessive paperwork, in contravention of the Paperwork Reduction Act. One member of the general public and 3 commenters from the research or scientific community noted, however, that the March 1989 proposal was carefully drafted to avoid unnecessary paperwork. Through our ongoing consultation with HHS and members of the IRAC, we have determined that certain paperwork and reporting requirements presented in the revised proposal can be coordinated with those already required under the PHS Policy, thereby reducing any additional burden that would be imposed upon grantee institutions. Certain other reporting requirements have been modified in the final rule to require less specific detail than originally proposed, and will also reduce the paperwork burden imposed upon research facilities. With these changes, explained in detail under the heading, "subpart C—Research Facilities," we believe we have reduced the paperwork and reporting requirements to the minimum necessary to effectuate the Act, and still enable us to administer the Act by determining whether research facilities are in compliance. We believe these regulations, as modified will not impede research.

We received 547 comments (103 from members of the general public, 442 from members of the research or scientific community, and 2 from dealers) stating that the revised proposal would interfere with research due to its rigidity, by not allowing the flexibility

and innovations necessary for the optimal care and treatment of animals. The final rules have been modified to allow research facilities greater flexibility in developing internal procedures to ensure compliance with the regulations. Ample opportunity for innovative research existed under the proposed rules, and is maintained in the final rules. The regulations provide for departures from the standards and regulations if justified by the principal investigator and approved by the Committee (final rule § 2.31(d)(1)). Under this provision, the research facility, through its Committee, is responsible for approving and allowing any innovations in research that are justified as necessary for scientific purposes. We do not agree with the commenters and believe that their concerns will not materialize upon implementation of the final rules.

Throughout this rulemaking process, we have remained cognizant that the Act proscribes the Secretary from interfering with research design or the performance of actual research. Section 13(a)(6) of the Act provides that "[n]othing in [the] Act (i) except as provided in paragraph (7) of [subsection (a)] shall be construed as authorizing the Secretary to promulgate rules, regulations, or orders with regard to the design, outlines, or guidelines of actual research or experimentation by a research facility as determined by such facility; (ii) except as provided * * * shall be construed as authorizing the Secretary to promulgate rules, regulations, or orders with regard to the performance of actual research or experimentation by a research facility as determined by such research facility; * * *" (7 U.S.C. 2143(a)(6)(A)(i) and (ii)). The regulations being promulgated today are necessary to effectuate the intent of the Act that animals used in biomedical research be provided humane care and treatment. They do not prescribe or interfere with research design or procedures.

Some commenters (28 members of the general public and 17 members of the research or scientific community) were concerned that the proposed regulations would result in research being conducted overseas, due to the added burdens and expense imposed upon the research community, and 5 commenters from the research or scientific community cautioned that the regulations will permit our competitors to overtake and surpass the lead we have enjoyed in biotechnology. We do not believe a significant amount of research activities will be conducted in other countries rather than the United States as a result of these rules. We also do not perceive that Congress or HHS would provide Federal funds for research conducted abroad to avoid the requirements of the Animal Welfare regulations. Similar concerns were raised in 1966 and 1967 when the Animal Welfare Act was first enacted and regulations were promulgated to implement it. History has shown that these concerns were not borne out. To the contrary, tremendous advancements in human and animal health have been made possible through continued support for biomedical research. We are not making any changes in the regulations on the basis of these concerns.

Nor do we agree with the 83 commenters from the research or scientific community who stated that many of the proposed revisions could be used to eliminate animals from biomedical research altogether.

The 1985 amendments to the Act impose specific requirements upon research facilities, including provisions ensuring adequate veterinary care, proper use of pain-relieving drugs, consideration of alternatives to the use of animals and to painful procedures, exercise for dogs, and psychological well-being of nonhuman primates, and some costs will necessarily be associated with these changes. In enacting the amendments, Congress specifically found that the use of animals is instrumental in certain research and education (7 U.S.C. 2131(b)). Congress also determined that the benefit to society of providing for the humane care and use of animals in research justifies its attendant costs. We believe that these final rules effectuate the intent of Congress without imposing an unnecessary, unreasonable, or unjustified financial burden.

Twenty commenters (2 members of the general public and 18 members of the research or scientific community) expresed concern that the proposed regulations, as revised in the March 1989 proposal, would discourage young people from entering medical research fields. We disagree. The requirements of the Animal Welfare Act to reduce pain and distress to animals, to reduce unnecessary duplication of experiments, to encourage development of alternative methods of research, and to provide a more humane environment for animals used in biomedical research, will not discourage young people from entering the field of medical research. We believe that greater concern for the humane care and use of animals may in fact encourage new scientists and foster greater support for biomedical research throughout our society.

One hundred eighty-three commenters (6 members of the general public and 177 members of the research or scientific community) protested that many of the proposed revisions to the regulations appeared to be a direct reaction to a vocal minority in the animal rights movement, whose purpose is to eliminate the use of animals in research entirely. This is a misperception. As noted above, the Act specifically states that "the use of animals is instrumental in certain research and education for advancing knowledge of cures and treatment for diseases and injuries which afflict both humans and animals; * * *" (7 U.S.C. 2131(b)). In passing the 1985 amendments to the Act, Congress responded to the concerns of the American public regarding the use of animals in biomedical research, and stated that alternatives to the use of animals should be encouraged, and unnecessary duplication of experiments on animals avoided (7 U.S.C. 2131(b)). These final regulations reflect the mandate of Congress that while animal experimentation shall continue, humane methods of animal care and use be implemented by biomedical research institutions.

We received 419 comments (74 from members of the general public, 223 from members of the research or scientific community, and 2 from dealers) stating that research would be impeded if research protocols and records are made part of the public record and subject to Freedom of Information Act (FOIA) requests. The commenters were concerned that public availability of this information would divulge trade secrets and would subject researchers to harrassment. Forty-six commenters (5 members of the general public and 41 members of the research or scientific community) were concerned with terrorist acts against researchers and their families as a result of public disclosure under the FOIA. One member of the research or scientific community stated that such records should be made part of the public record.

The regulations, as revised in this final rule, require that a summary of exceptions to the standards and regulations be attached to the research facility's annual report (final rule § 2.36(b)(3)). Neither the research "protocol", nor the animal care and use procedure that will be followed in carrying out the research, is required in the annual report. APHIS inspectors are authorized to inspect such records under the Act, but there is no requirement in the final regulations that the records be

submitted to and maintained by APHIS as a regular practice. Therefore, these records generally are not agency records available under the Freedom of Information Act. Furthermore, APHIS records of inspections [VS Form 18-8] and the annual reports submitted by research facilities list animal use sites at research facilities. They do not list researchers by name and address. We believe the commenters concerns are unwarranted, and that no further change is needed in the final rule.

Three hundred twenty-six commenters [93 members of the general public, 231 members of the research or scientific community, and 2 dealers] asserted that under the revised proposal, an adversarial relationship between veterinarians and researchers would result. We do not agree with this characterization. We revised our initial proposal to clarify areas of responsibility to avoid potential conflict, and to ensure that provision is made for proper veterinary care in the planning and conduct of animal care and use procedures. This allocation of authority by the research facility to the attending veterinarian is maintained in the final rule. Section 2.33[a][2] requires that a facility's attending veterinarian be given appropriate authority to ensure that adequate veterinary care is provided, and to oversee animal care and use. These areas are within the expertise of doctors of veterinary medicine. In recognition of this fact, section 13[a][3][C] of the Act requires that a veterinarian be consulted in planning a potentially painful procedure [7 U.S.C. 2143[a][3][C]], and the final rule reflects this determination of Congress [final rule § 2.33]. As we stated in the revised proposal, we do not regard this interaction as an impediment to research, but rather as a necessary ingredient of the research facilities' commitment to assuring animal welfare.

We received 269 comments [78 from members of the general public, 189 from members of the research or scientific community, and 2 from dealers] stating that the Secretary does not have the authority to establish committees with power to review or disapprove of research protocols for any reason, since this authority would deprive researchers of the scientific discretion necessary for the conduct of research. The revised proposal was explicitly clear that Committees would be authorized to review the animal care and use procedure to be employed in a proposed research activity, in accordance with the requirements of the Act, and that this authority did not extend to research "protocol" approval. It is the mandate of Congress that Committees assess animal care, treatment, and practices [7 U.S.C. 2143(b)(1)].

As we explained in detail in the supplementary information accompanying the revised proposal, it is necessary that Committees review the animal care and use procedures proposed to be followed in the conduct of research in order for a research facility to assure us that it is in compliance with the Act and regulations. This authority is limited to the animal care and use portion of a proposal to determine how the research will treat or affect an animal and its condition, and the circumstances under which the animal will be maintained. It does not extend to evaluating the design, outlines, guidelines, and scientific merit of proposed research [54 FR 10849]. We have attempted to clarify this point further in the final rule, and put such concerns to rest, by stating that the Committee *shall* function as an agent of the research facility [final rule § 2.31(c)]. In that capacity, the Committee shall review those components of proposed activities, or proposed changes in activities, related to the care and use of animals and determine that they are in accordance with the Animal Welfare regulations unless otherwise justified [final rule § 2.31(d)(1)].

We received 254 comments [70 from members of the general public, 182 from members of the research or scientific community, and 2 from dealers stating that APHIS's regulatory role should be limited to detecting deviations from approved activities, and should not extend to formulation of proposals. Upon implementation of the final rules, APHIS's role will be to administer and enforce the Animal Welfare Act and regulations to ensure compliance. The Act itself provides that certain procedures and safeguards must be followed in research involving potentially painful procedures in order to ensure the humane care and use of animals and that adequate veterinary care is provided [7 U.S.C. 2143(a)(3)]. Our regulatory authority extends to ensuring that these procedures and safeguards are adequately addressed and adhered to. We repeat here, for the benefit of the commenters, that we acknowledge the limitation on our authority to promulgate rules, regulations, or orders with regard to the design, outlines, guidelines, or performance of actual research [7 U.S.C. 2143(a)(6)(A)].

Four hundred eighty-five commenters [68 members of the general public, 315 members of the research or scientific community, and 2 dealers] objected to the tone of our March 1989 regulatory proposals, stating that they imply that research [and researchers] is [are] unethical. We do not intend to imply any ethical judgments in these regulations. In amending the Act in 1985, Congress determined that "the use of animals is instrumental in certain research and education for advancing knowledge of cures and treatment for diseases and injuries which afflict both humans and animals; * * *" [7 U.S.C. 2131(b)]. However, Congress also determined that certain measures must be prescribed and followed by research facilities to "help meet the public concern for laboratory animal care and treatment * * *" [7 U.S.C. 2131(b)]. We are promulgating these regulations which govern the care, use, treatment, and handling of warm-blooded animals by research facilities and other entities, to carry out the mandate of Congress.

Comments on Specific Interrelationships Between Parts 2 and 3

We received 392 comments [95 from members of the general public, 295 from members of the research or scientific community, and 2 from dealers] stating that part 1 [Definition of terms] and part 2 [Regulations] of the regulations should not be made final without the final rule for part 3 [Standards], because they are interdependent. We also received 249 comments [68 from members of the general public, 177 from members of the research or scientific community, and 4 from dealers] stating that parts 1 and 2 should not become final without part 3 in order to be cost-effective.

We have considered the public's comments on the interrelationship of the regulations and standards and have revised the final rule accordingly. We believe that parts 1 and 2 of the regulations can be effectively implemented without further delay. Standards governing the humane handling, care, treatment, and transportation of the warm-blooded animals covered by the Act are contained in part 3 of the regulations. Although we are proposing to amend those standards, we believe that these final rules can now be implemented using the existing standards. Prompt implementation of these final rules will carry out many of the provisions for animal welfare mandated by Congress in amending the Act. No further delay is necessary to ensure that adequate veterinary care is provided to all animals under the Act and that pain-relieving drugs are used where appropriate.

Comments on the interrelationship of the terms contained in parts 2 and 3 of the regulations that are defined in part 1 are discussed in companion docket No. 89-130, published elsewhere in this issue of the **Federal Register**. In that document, we address comments suggesting that additional definitions or clarifications are necessary.

We received 480 comments (478 from members of the general public and 2 from members of the research or scientific community) expressing support for parts 1 and 2 as they relate to part 3.

Three dealers and one member of the general public requested that we clarify when an exhibitor should be registered under part 2, subpart B, or licensed, in accordance with subpart A and the term, "Class "C" licensee." Persons who meet the definition of the term "Exhibitor" provided in § 1.1 of the final rule must obtain a Class "C" license if their business involves the showing or displaying of animals to the public. Section 2.25 requires that all other exhibitors register in accordance with the requirements of subpart B of the final rule, unless they are exempt from the licensing requirements under section 3 of the Act. Section 3 exempts "any retail pet store or other person who derives less than a substantial portion of his income (as determined by the Secretary) from the breeding and raising of dogs or cats on his own premises and sells any such dog or cat to a dealer or research facility * * *" (7 U.S.C. 2133). We believe that the definitions provided in the final rule for "Exhibitor" and "Class "C" licensee" are clear, and that no further clarification of the registration regulations in subpart B are necessary.

One member of the research or scientific community requested that we clarify the Committee's responsibility regarding animals that are not covered by the Act. The Animal Welfare Act and regulations apply only to regulated animals. The term "animal" is defined in the final rule for part 1 for purposes of these regulations. The Committee has no responsibilities under these regulations for animals that are not covered by the Act.

We received several comments objecting to the requirement of revised proposal § 2.30(g) which would require that exceptions to the standards and regulations be permitted by research facilities only when necesary in order to accomplish the research design, specified in the proposed animal care and use procedure submitted to the Committee for approval, explained in detail, and approved by the Committee. Paragraph (g) provided that the principal investigator must first file a report with the Committee "explaining the areas of noncompliance in detail." Three commenters (1 member of the general public and 2 members of the research or scientific community) objected that requiring a detailed explanation of deviations or exceptions to compliance with the regulations and standards will delay research.

The Act requires that exceptions to the standards be allowed only when specified by research protocol (7 U.S.C. 2143(a)(3)(E)). Any such exceptions must be detailed and explained in the research facility's annual report and filed with the Committee (7 U.S.C. 2143(a)(3)(E)). It is the responsibility of the research facility to ensure that it is in compliance with the Act and regulations. In order to do so the final regulations provide that the Committee, as an agent of the research facility, shall review all proposed activities and proposed changes on ongoing activities, to determine whether they are in compliance, or whether an exception is justified. Under the final rule, the principal investigator must present an acceptable justification for the exception, in writing. A summary of all such exceptions must also be attached to the facility's annual report in accordance with the requirements of the Act (final rule § 2.36(b)(3)). We believe that the burden imposed upon principal investigators in explaining how their proposal departs from the regulations and standards, and justifying the proposed exception, is reasonable and necessary to keep the institution informed of research activities and in compliance with the Act. The final rule provides means by which the research facilities can ensure that Committee review is provided without undue delay. We do not believe that this requirement, as revised in the final rule, will delay research.

Four members of the research or scientific community objected to the term, "areas of noncompliance" and suggested that we refer to "scientifically justified exceptions to the standards" instead. As noted briefly above, and explained in greater detail under the heading, "subpart C—Research Facilities", § 2.31(d)(1) of the final rule is revised to require that the Committee review proposed activities to determine that the animal care and use components of those activities are in accordance with the regulations, "unless acceptable justification for a departure is presented; * * *" (final rule § 2.31(d)(1)). This language is consistent with the PHS Policy and is more appropriate, since an approved departure from the regulations would not be deemed a violation of the Act, as the term "noncompliance" may connote.

One member of the research or scientific community objected to considering scientifically necessary exceptions to the regulations as being areas of noncompliance or deviations which must be explained in detail by the principal investigator and included in a written report that is attached to the annual report. As noted above, the Act requires that exceptions to the standards be explained in a written report and included in the research facility's annual report (7 U.S.C. 2143(a)(3)(E)). Under the final rule, therefore, the research facility must assure that it has required "that exceptions to the standards and regulations be specified and explained by the principal invetigator and approved by the IACUC." (Final rule § 2.31(d)(3)). We are requiring that a "summary of all such exceptions * * *" be attached to the annual report (final rule § 2.36(b)(3)). The terms "areas of noncompliance" or "deviations" used in the revised proposal are referred to as "departures" from the regulations, or "exceptions" in the final rule, for the reason set forth immediately above. Therefore, scientifically necessary exceptions must be explained by the principal investigator and described, in writing, in the facility's annual report, contrary to the commenter's assertion.

Four commenters (2 members of the general public and 2 members of the research or scientific community) opposed the requirement that written reports of exceptions to the standards and regulations be attached to the annual report, as required under revised proposal § 2.30(g). This requirement is statutorily mandated, as set forth above, and is retained in the final rule (final rule § 2.31(d)(3)). We have modified it to require summaries of such exceptions, however, as explained in greater detail under the heading, "Subpart C—Research facilities", subheading, "Annual report."

We received 628 comments (619 from members of the general public and 9 from members of the research or scientific community) endorsing the requirements of revised proposal § 2.30(h), "Exercise for dogs and psychological well-being of nonhuman primates." It would require that "[t]he research facility shall establish, in consultation with the attending veterinarian, written procedures and systems for the exercise of dogs and for the psychological well-being of primates in accordance with the regulations and standards, and a record system documenting that such a procedure or

system is being carried out." We also received 203 comments (196 from members of the general public, 4 from members of the research or scientific community, 1 from a dealer) supporting the requirement for documentation of the release of dogs for exercise (revised proposal § 2.30(h) and proposed § 3.07(d)), and 193 comments (189 members of the general public and 4 members of the research or scientific community) supporting the requirement for documentation of primate exercise and psychological well-being (revised proposal § 2.30(h) and proposed § 3.81(c)). Fourteen commenters (1 member of the general public and 13 members of the research or scientific community) opposed the requirement for written procedures and record systems, and 303 commenters (74 members of the general public, 227 members of the research or scientific community, and 2 dealers) stated that the requirements of revised proposal § 2.30(h), if included in the final rule, could not be met in the absence of the standards set forth in part 3. In addition, although the revised proposal made clear that the procedures may be included in the facility's standard operating procedure and need not be a separate document, members of the IRAC expressed concern in the course of our consultation, that the requirement for written procedures for the exercise of dogs and recordkeeping systems for documenting exercise would be administratively burdensome.

We proposed that recordkeeping systems be maintained to ensure compliance, since exercise could not otherwise be verified. We continue to endorse this approach, as stated in the supplementary information accompanying the revised proposal. However, requirements for exercise of dogs and for promoting the psychological well-being of nonhuman primates will, upon publication of a final rule, be set forth in subparts A and D of part 3 of the regulations. Until the proposed regulations for part 3 are published as a final rule, there are no such procedures and systems to record. We believe that making this requirement of part 2 final before the promulgation of standards for exercise and psychological well-being would be premature, confusing, and difficult to enforce. We are therefore removing from the final rule for part 2 the requirement that a record system documenting that a procedure or system for exercise of dogs and for the psychological well-being of nonhuman primates be established, pending promulgation of a final rule for part 3.

Three members of the research or scientific community commented that all Federal research facilities should be covered by the regulations. The Act provides that Federal research facilities shall establish Committees having the same composition and responsibilities required at nonfederal research facilities (7 U.S.C. 2143(c)). It also provides that Federal research facilities shall comply with the standards and requirements promulgated under Section 13 (a), (f), (g), and (h) of the Act (7 U.S.C. 2144). (This section reference appears in the Act as Section 13 (a), (g), (h), and (i) due to a drafting error which created two paragraphs designated as (f).) Although we do not exercise authority to inspect Federal research facilities, they must comply with the standards promulgated under the Act. The requirement that Federal facilities maintain Committees *having the* same composition, duties, and responsibilities required of other research facilities is contained in § 2.37 of the final rule.

Two members of the research or scientific community commented that pounds and shelters should be regulated under the Act. We do not have authority under the Act to regulate governmentally owned and operated pounds and shelters. We do regulate private or contract pounds and shelters, however, if they meet the definition of a dealer, as set forth in final rule § 1.1. Regulations governing their operations are set forth in § 2.132 of the final rule.

Two hundred forty-two commenters (67 members of the general public, 173 members of the research or scientific community, and 2 dealers) objected to the revised proposal arguing that there is no proof that large numbers of stolen animals end up at research facilities. Certain of the provisions in the regulations are intended to prevent this from occurring (*see, e.g.*, final rule §§ 2.38 (d), (j), (k), 2.60, 2.101)).

One of the original findings of Congress underlying enactment of the Animal Welfare Act in 1966 was the need "to protect the owners of animals from the theft of their animals by preventing the sale or use of animals which have been stolen." (7 U.S.C. 2131(b)). This is still a valid concern of Congress and the public, and therefore the Department. Regulations intended to prevent the sale of stolen animals to research facilities and the use by research facilities of stolen animals are therefore included in the final rule for part 2.

Public Comments on Regulatory Impact Analysis and Regulatory Flexibility Act Analysis

The anticipated economic impact of implementing the 1985 amendments to the Animal Welfare Act has generated much interest, discussion, and controversy. The Department conducted a regulatory impact analysis of the proposed rules as required by Executive Order 12291. The analysis determined that implementation of the proposed rules would have a cost impact in excess of $100 million on the economy, thus it would be a "major rule." The analysis of cost impacts was based on our best assessment; available information indicated that the costs to regulated establishments would amount to $207 million for annual operating expenditures and $876 million for capital investments.

We received 632 comments (3 from the research community, 2 from dealers, and 627 from the general public) noting that the regulatory impact analysis contained "overinflated" cost estimates. Only 1 of the comments from the general public provided detailed information of compliance costs for each new provision in the proposed rules. The rest of the comments contained a formatted statement indicating that costs in the analysis were "overinflated" and the proposed rules asked for nothing more than a well-run animal facility already provided for regulated animals.

We also received 270 comments (91 members of the general public, 177 members of the research or scientific community, and 2 dealers) noting that the cost estimates in the regulatory impact analysis were too low. Again, only 1 commenter from the research community provided detailed information and different compliance cost estimates of implementing the proposed rules. The commenter estimated that implementation of the proposed rules will cost regulated establishments more than $450 million annually plus a capital investment of at least $1.6 billion over the next several years.

In conducting the regulatory impact analysis, the Department decided early in the analysis that attempting to construct a coherent analytical framework to estimate potential compliance costs was inappropriate. Time and resources did not allow the traditional economic approach of conceptualizing and estimating an analytical framework. Also, a single framework would not have provided all useful answers to all questions on anticipated cost impacts because of the

complexity of factors being measured, the lack of statistical data sources, and the diversity of regulated establishments. Instead, the Department relied on several informational sources such as expert opinion from across the country, our inspection of regulated sites, and our own experience in administering the Animal Welfare regulations. The cost estimates represented best efforts by the Department and are not to be construed as exact estimates of compliance due to obvious limitations, as stated in the analysis.

However, we disagree with those commenters who stated that the potential costs on regulated establishments were "overinflated." The proposed rules contained many new animal welfare provisions required by the statute which are not presently prescribed in the existing regulations. Compliance with these new provisions will require regulated establishments to update their facilities and practices so that the level of humane care and treatment afforded to regulated animals will increase. The derivation of cost estimates provided by the commenter from the research community which doubled the cost estimates in the regulatory impact is also subject to data and analytical constraints. Furthermore, the commenter provided insufficient detail, methodology, and data to support its cost estimates. We believe that these cost estimates represent a "worst case" scenario of implementing the proposed rules.

Sixty-six commenters from the general public, 168 commenters from the research or scientific community, and 2 dealers stated that the regulatory impact analysis did not contain sufficient detail to explain the discrepancies between the Department's cost estimates (referenced above), and those submitted by a commenter from the research or scientific community. The regulatory analysis provides an internal mechanism for the Department to promulgate new rules or revise existing rules based on information which is available to the Department. It is impossible for the Department to compare its own findings in the regulatory analysis with those provided by a commenter after the proposed rules have been made public.

Four hundred ninety-two commenters (275 from the research or scientific community, 114 from the general public, and 3 dealers) stated that the proposed regulations would inflate the cost of animal research making it cost prohibitive. Two hundred sixty-one commenters (68 members of the general public, 168 members of the research or scientific community, and 25 dealers) also stated that the proposed rules will cost too much to implement and will put small dealers out of business. Two hundred forty-three commenters (66 members of the general public, 175 members of the research or scientific community, and 2 dealers) also stated that the proposed rules will cost too much and will put small researchers out of business. In addition, 70 commenters from the general public, 179 commenters from the research community, and 2 dealers were shocked that the Department discounted the impact of the proposed rules believing that no establishment would abandon the use of animals in biomedical research due to increased compliance costs. Most of these commenters also stated that the increased costs for animal research are important, and when coupled with the delay in research advances, would make the real costs staggering.

The regulatory review has indicated that a cost impact on animal research and small entities would occur. Moreover, the regulatory review has also indicated that the cost impact of the regulations result from the implementation of the new provisions in the 1985 amendments to the Animal Welfare Act. The Department has not discounted the potential economic effects of the proposed rules on biomedical research using animals as mere cost increases. We have acknowledged that the overall impact on biomedical research is difficult to assess. Whether biomedical research facilities would abandon the use of animals depends on the extent of compliance costs to be imposed on each facility. Biomedical research facilities vary extensively as to their research needs, operations, animal premises, and their inventory of regulated species.

In developing final rules, the Department has considered and will continue to consider regulations that will impose the least cost on regulated establishments within statutory goals. The Department does not consider the regulations to be imposing prohibitive costs on regulated establishments. Most facilities meeting or exceeding present compliance requirements may not be greatly impacted by the regulations, except for the new provisions as stated in the amendments.

Two hundred ninety-two commenters (72 members of the general public, 178 members of the research or scientific community, and 2 dealers) indicated that the Department has failed to do a cost-benefit analysis as required by Executive Order 12291. Ninety-three members of the general public, 301 members of the research or scientific community, and 2 dealers stated that the regulations provided no benefit to animals or improvements in animal care.

The general requirements for a regulatory impact analysis under Executive Order 12291 of proposed federal rules require that costs and benefits be identified and examined. They also require that regulatory objectives be chosen to maximize net benefits to society or involve the least cost to society. The regulatory analysis examined the presence of benefits to society and animals arising from the regulatory proposals and indicated that these benefits could not be properly quantified. In the absence of actual dollar figures for benefits, it was impossible to estimate the net potential benefits from the regulations.

The Department disagrees with the opinion that animals will not receive improved animal care or benefits under the proposed rules. There has been considerable scientific data and increased public opinion that supports the intent of Congress to increase the level of animal care and treatment afforded to animals in regulated establishments. Requirements that provide for better and enriched animal housing environments, appropriate veterinary care, procedures that minimize animal pain and discomfort, and alternatives to animal research are some of the factors which support the increased level of welfare and benefits to regulated animals.

Seventy-four commenters members of the general public, 172 members of the research or scientific community, and 2 dealers stated that the Department has failed to consider alternatives that will achieve statutory goals and involve the least cost to society. The Department disagrees with these commenters. In developing the proposed rules, the Department has sought comments and input from the regulated establishments, the general public, and interested Federal agencies. Previous proposals contain extensive discussion and explanation of alternative provisions for each new revision or change required by the amendments. The Department will also finalizes rules after all relevant factors are considered, including least costly alternatives, in achieving statutory goals.

Statutory Authority

This rule is issued pursuant to the Animal Welfare Act (Act), as amended, 7 U.S.C. 2131–2157. Congress recently added significantly to the Secretary's responsibilities under the Act,

particularly with regard to the use of animals by research facilities, in the Food Security Act of 1985, Public Law No. 99-198, approved December 23, 1985. The declared policy of the Act is to ensure that animals intended for use in research facilities, as pets, or for exhibition purposes, are provided humane care and treatment; to assure the humane treatment of animals during transportation; and to prevent the sale of stolen animals.

The Act requires that animal dealers and exhibitors obtain a license from the Secretary, and that research facilities, carriers, and intermediate handlers register with the Secretary. The Act directs the Secretary to issue specific regulations concerning, *inter alia* recordkeeping, veterinary care, handling, transportation, identification of animals, and holding period requirements. In addition, the 1985 amendments require the Secretary to issue expanded regulations governing the use of animals in research facilities. Section 21 of the Act continues to authorize the Secretary to issue such regulations as he deems necessary to effectuate the purposes of the Act.

The recent amendments mandate that these regulations are to include standards for care, treatment, and practices in experimental procedures which will minimize pain and distress. The Secretary is to require that researchers consider alternatives to painful procedures and that, with regard to painful procedures, researchers must consult a veterinarian; use adequate tranquilizers, anesthetics, and analgesics; and provide for adequate pre- and post-surgical care. Moreover, exceptions to these standards may be made only when specified by research protocol and explained in a report mandated in the Act.

The Act also mandates that the Secretary issue regulations requiring research facilities to show and report that they are complying with the Act and that they are following professionally acceptable standards in the care and treatment of animals during research. The Act directs the Secretary to require each research facility to establish a committee to assess the facility's use and treatment of animals. The Act specifies the composition of the committee, including the requirement that each committee must be composed of at least three members and that each committee must have at least one member who is a veterinarian and at least one who represents the community interest in proper animal care. The Act mandates many of the committee's responsibilities, including that it inspect and report at least semi-annually on the condition and use of animals and report any violations of the standards. The Secretary is also to require each research facility to provide training for all personnel involved in animal care.

This rule contains regulations required by the 1985 amendments as well as modifications to existing regulations based on the Department's experience in administering the Act.

Executive Order 12291

The Department has examined the economic impact of this final rule in accordance with Executive Order 12291.

Amendments to the Animal Welfare Act require changes in the existing Animal Welfare regulations. The Department has finalized revisions to part 2 of the Animal Welfare regulations under its statutory authority. The final regulations for part 2 contain revisions and new requirements intended to improve the welfare of animals and the regulated public's understanding of the regulations, thereby increasing compliance and effectiveness. In developing these regulations, the Department has given full consideration to the input and comments received from regulated establishments, the general public, and interested Federal agencies to previous alternative regulatory proposals. These regulations are consistent with and do not contradict other Federal regulations, policies, or guidelines on laboratory animal care, use, and treatment practices.

The regulatory analysis focuses on the changes to part 2 of the Animal Welfare regulations required by the amendments. The analytical emphasis is on the incremental costs to be imposed on regulated establishments (research facilities, breeders, dealers, and exhibitors) when these regulations become effective. These compliance costs are attributed to the statute itself and are mainly due to new requirements for the establishment and maintenance of institutional animal care and use committees in research facilities, programs of adequate veterinary care, and the use of procedures to ensure that animal pain and distress are minimized.

Revisions to part 2 of the regulations will require Federal and nonfederal research facilities to spend between $43.5 and $132.8 million in capital expenditures to renovate, equip, replace, or construct aseptic surgical facilities, and provide for adequate pre-operative and post-operative care of animals. Only those facilities performing surgery on regulated species of animals will be affected. A range is provided because the Department is unaware of the degree to which research facilities currently comply with these standard veterinary procedures in the absence of specific regulations. The Department estimates $33 million in additional annual compliance costs for Federal and nonfederal research institutions to comply with the new regulations and requirements for the operation of the institutional animal care and use committees, increased responsibilities for attending veterinarians, and increased recordkeeping requirements. These costs represent additional costs for laboratory personnel and the need for additional personnel in research facilities.

Overall, the Department does not anticipate a significant economic impact from part 2 of the regulations on biomedical research, testing, and education, since current outlays are estimated to be in excess of $14 billion per year. In terms of annual compliance costs, the regulatory impact on biomedical research would account for far less than one percent (0.2%) of the aggregate annual outlays. However, there could be small, but important, implications and distributional effects associated with allocating additional funds or expenditures for compliance with the regulations.

Licensees (breeders, dealers, and exhibitors) would be required to spend an additional $0.6 million to comply with the revised requirements for licensing, animal identification, and adequate veterinary care. With the exception of increases in annual license fees, the additional cost of these new requirements are also attributed to the statute itself. These additional costs would not have any adverse effects on the ability of licensees to continue animal ventures and the implementation of the regulations will assist the Department by enhancing traceability of animals purchased, sold or transported. These costs could also be passed on to other regulated establishments or consumers who purchase their animals.

Other economic impacts that are examined but not quantified in this analysis include the benefits which would result from increased levels of humane care and treatment of animals used for research, testing, teaching, exhibition and business ventures. The main intent of the amendments and the regulations is to increase the welfare of animals. Direct benefits accrue to society based on perceptions of increased improvements in the manner in which animals would be cared for under the new regulations. Animal research will benefit from the avoidance of unnecessary duplication of animal

experiments or protocols, increased exchange of technical information, and the renewed emphasis on and interest in the use of scientifically and economically feasible alternatives to animal experimentation.

Based on the analysis of potential cost impacts, the Department has determined that implementing parts 1 and 2 of the regulations may constitute a "major rule." The estimated total additional compliance costs for part 2 of the regulations are treated together with the economic implications that part 3—"Standards" may have on regulated establishments. The amendments mandate changes in animal housing, environmental enrichments, and exercise and socialization of dogs. Available information indicates that the bulk of the regulatory impact will be due to new requirements for the exercise of dogs and a physical environment that promotes the psychological well-being of non-human primates, specific provisions required by the amendments. The Department considers the changes in all three parts of the Animal Welfare regulations will be a "major rule" based on anticipated cost increases in excess of $100 million for animal uses, care, and treatment. For that purpose, the Department has considered and will continue to examine least cost feasible alternatives, whenever appropriate and within statutory goals, in developing the final Animal Welfare regulations.

Regulatory Flexibility Act

The Department has analyzed the potential impact on small entities of this final rule for part 2 of the Animal Welfare regulations as required by the Regulatory Flexibility Act (Pub. L. 96-354).

Based upon our analysis, the Department determines that this final rule could affect all small regulated entities, primarily by increases in annual license fees, and identification requirements for dogs and cats. However, the economic impacts would not be significant. The greatest economic burden of this rule would be imposed on large regulated entities and large research facilities. It is anticipated that the largest economic impact on small entities would result from changes in part 3—"Standards." Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with state and local officials. (See 7 CFR part 3015, subpart V.)

Paperwork Reduction Act

The information collection and recordkeeping provisions that are included in the final rules amending 9 CFR parts 1 and 2 have been submitted for approval to the Office of Management and Budget (OMB), in accordance with the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35) under control number 0579-0036, and upon approval, will become effective upon October 30, 1989. The Department has requested that OMB conclude its review no later than October 30, 1989.

The public reporting burden for this collection of information is estimated to average 0.96 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The public recordkeeping burden is estimated to average 4.0 annual hours per recordkeeper.

Send written comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the U.S. Department of Agriculture, Clearance Officer, OIRM, Room 404W, Washington, DC 20250; and to the Office of Management and Budget, Paperwork Reduction Project (OMB Control No. 0579-0036), Washington, DC 20503.

List of Subjects

9 CFR Part 2

Licensing, Registration, Identification of animals, Records, Institutional animal care and use committees and adequate veterinary care, Miscellaneous.

9 CFR Part 3

Animal welfare, Humane animal handling, Pets, Transportation.

Accordingly, based on the rationale set forth in the preamble, we are amending 9 CFR parts 2 and 3 as follows:

1. Part 2 is revised to read as follows:

PART 2—REGULATIONS

Subpart A—Licensing

Sec.

Subpart B—Registration

Subpart C—Research Facilities

Subpart D—Attending Veterinarian and Adequate Veterinary Care

Subpart E—Identification of Animals

Subpart F—Stolen Animals

Subpart G—Records

Subpart H—Compliance With Standards and Holding Period

Subpart I—Miscellaneous

Authority: 7 U.S.C. 2131–2157; 2.17, 2.51, and 371.2(g).

Subpart A—Licensing

§ 2.1 Requirements and application.

(a)(1) Any person operating or desiring to operate as a dealer, exhibitor, or operator of an auction sale, except persons who are exempted from the licensing requirements under paragraph (a)(3) of this section, must have a valid license. A person must be 18 years of age or older to obtain a license. A person seeking a license shall apply on a form which will be furnished by the APHIS, REAC Sector Supervisor in the State in which that person operates or intends to operate. The applicant shall provide the information requested on the application form, including a valid mailing address through which the licensee or applicant can be reached at all times, and a valid premises address where animals, animal facilities, equipment, and records may be inspected for compliance. The applicant shall file the completed application form with the APHIS, REAC Sector Supervisor.

(2) If an applicant for a license or license renewal operates in more than one State, he or she shall apply in the State in which he or she has his or her principal place of business. All premises, facilities, or sites where such person operates or keeps animals shall be indicated on the application form or on a separate sheet attached to it. The completed application form, along with the application fee indicated in paragraph (d) of this section, and the annual license fee indicated in table 1 or 2 of § 2.6 shall be filed with the APHIS, REAC Sector Supervisor.

(3) The following persons are exempt from the licensing requirements under section 2 or section 3 of the Act:

(i) Retail pet stores which sell nondangerous, pet-type animals, such as dogs, cats, birds, rabbits, hamsters, guinea pigs, gophers, domestic ferrets, chinchilla, rats, and mice, for pets, at retail only: *Provided, That,* Anyone wholesaling any animals, selling any animals for research or exhibition, or selling any wild, exotic, or nonpet animals retail, must have a license;

(ii) Any person who sells or negotiates the sale or purchase of any animal except wild or exotic animals, dogs, or cats, and who derives no more than $500 gross income from the sale of such animals to a research facility, an exhibitor, a dealer, or a pet store during any calendar year and is not otherwise required to obtain a license;

(iii) Any person who maintains a total of three (3) or fewer breeding female dogs and/or cats and who sells only the offspring of these dogs or cats, which were born and raised on his or her premises, for pets or exhibition, and is not otherwise required to obtain a license;

(iv) Any person who sells fewer than 25 dogs and/or cats per year which were born and raised on his or her premises, for research, teaching, or testing purposes or to any research facility and is not otherwise required to obtain a license. The sale of any dog or cat not born and raised on the premises for research purposes requires a license;

(v) Any person who arranges for transportation or transports animals solely for the purpose of breeding, exhibiting in purebred shows, boarding (not in association with commercial transportation), grooming, or medical treatment, and is not otherwise required to obtain a license;

(vi) Any person who buys, sells, transports, or negotiates the sale, purchase, or transportation of any animals used only for the purposes of food or fiber (including fur);

(vii) Any person who breeds and raises domestic pet animals for direct retail sales to another person for the buyer's own use and who buys no animals for resale and who sells no animals to a research facility, an exhibitor, a dealer, or a pet store (e.g., a purebred dog or cat fancier) and is not otherwise required to obtain a license;

(viii) Any person who buys animals solely for his or her own use or enjoyment and does not sell or exhibit animals, or is not otherwise required to obtain a license;

(b) Any person who sells fewer than 25 dogs or cats per year for research or teaching purposes and who is not otherwise required to obtain a license may obtain a voluntary license, provided the animals were born and raised on his or her premises. A voluntary licensee shall comply with the requirements for dealers set forth in this part and the Specifications for the Humane Handling, Care, Treatment, and Transportation of Dogs and Cats set forth in part 3 of this subchapter and shall agree in writing on a form furnished by APHIS to comply with all the requirements of the Act and this subchapter. Voluntary licenses will not be issued to any other persons. To obtain a voluntary license the applicant shall submit to the APHIS, REAC Sector Supervisor the application fee of $10 plus an annual license fee. The class of license issued and the fee for a voluntary license shall be that of a Class "A" licensee (breeder). Voluntary licenses will not be issued to any other persons or for any other class of license.

(c) No person shall have more than one license.

(d) A license will be issued to any applicant, except as provided in §§ 2.10 and 2.11, when the applicant:

(1) Has met the requirements of this section and of §§ 2.2 and 2.3; and

(2) Has paid the application fee of $10 and the annual license fee indicated in § 2.6 to the APHIS, REAC Sector Supervisor and the payment has cleared normal banking procedures.

(e)(1) On or before the expiration date of the license, a licensee who wishes a renewal shall submit to the APHIS, REAC Sector Supervisor a completed application form and the application fee of $10, plus the annual license fee indicated in § 2.6 by certified check, cashier's check, personal check, or money order. A voluntary licensee who wishes a renewal shall also submit the $10 application fee plus an annual license fee. An applicant whose check is returned by the bank will be charged a fee of $15 for each returned check. One returned check will be deemed nonpayment of fees and will result in denial of license. Payment of fees must then be made by certified check, cashier's check, or money order. An applicant will not be licensed until his or her payment has cleared normal banking procedures.

(2) The $10 application fee must also be paid if an applicant is applying for a changed class of license. The applicant may pay such fees by certified check, cashier's check, personal check, or money order. An applicant whose check is returned by a bank will be charged a fee of $15 for each returned check and will be required to pay all subsequent fees by certified check, money order, or cashier's check. A license will not be issued until payment has cleared normal banking procedures.

(f) The failure of any person to comply with any provision of the Act, or any of the provisions of the regulations or standards in this subchapter, shall constitute grounds for denial of a license; or for its suspension or revocation by the Secretary, as provided in the Act.

§ 2.2 Acknowledgment of regulations and standards.

APHIS will supply a copy of the applicable regulations and standards to

the applicant with each request for a license application or renewal. The applicant shall acknowledge receipt of the regulations and standards and agree to comply with them by signing the application form before a license will be issued or renewed.

§ 2.3 Demonstration of compliance with standards and regulations.

(a) Each applicant must demonstrate that his or her premises and any animals, facilities, vehicles, equipment, or other premises used or intended for use in the business comply with the regulations and standards set forth in parts 2 and 3 of this subchapter. Each applicant for an initial license or license renewal must make his or her animals, premises, facilities, vehicles, equipment, other premises, and records available for inspection during business hours and at other times mutually agreeable to the applicant and APHIS, to ascertain the applicant's compliance with the standards and regulations.

(b) In the case of an application for an initial license, the applicant must demonstrate compliance with the regulations and standards, as required in paragraph (a) of this section, before APHIS will issue a license. If the applicant's animals, premises, facilities, vehicles, equipment, other premises, or records do not meet the requirements of this subchapter, APHIS will advise the applicant of existing deficiencies and the corrective measures that must be completed to come into compliance with the regulations and standards. The applicant will have two more chances to demonstrate his or her compliance with the regulations and standards through re-inspection by APHIS. If the applicant fails the third inspection he or she will forfeit the application fee and cannot re-apply for a license for a period of 6 months following the third inspection. Issuance of the license will be denied until the applicant demonstrates upon inspection that the animals, premises, facilities, vehicles, equipment, other premises and records are in compliance with all regulations and standards in this subchapter.

§ 2.4 Non-interference with APHIS officials.

A licensee or applicant for an initial license shall not interfere with, threaten, abuse (including verbally abuse), or harass any APHIS official in the course of carrying out his or her duties.

§ 2.5 Duration of license and termination of license.

(a) A license issued under this part shall be valid and effective unless:

(1) The license has been revoked or suspended pursuant to section 19 of the Act.

(2) The license is voluntarily terminated upon request of the licensee, in writing, to the APHIS, REAC Sector Supervisor.

(3) The license has expired or been terminated under this part.

(4) The applicant has failed to pay the application fee and the annual license fee as required in §§ 2.1 and 2.6.

There will be no refund of fees if a license is terminated prior to its expiration date.

(b) Any person who is licensed must file an application for a license renewal and an annual report form (VS Form 18-3) as required by § 2.7, and pay the required fees, on or before the expiration date of the present license or the license shall expire and automatically terminate on its anniversary date. The licensee will be notified by certified mail at least 60 days prior to the expiration date of the license. Failure to comply with the annual reporting requirements, or to pay the required license fees prior to the expiration date of the license, shall result in automatic termination of such license on the anniversary date of the license.

(c) Licensees must accept delivery of registered mail or certified mail notice and provide the APHIS, REAC Sector Supervisor notice of their address in conformity with the requirements in § 2.1.

(d) Any person who seeks the reinstatement of a license that has been automatically terminated must follow the procedure applicable to new applicants for a license set forth in § 2.1.

(e) Licenses are issued to specific persons for specific premises and do not transfer upon change of ownership, nor are they valid at a different location.

(f) A license which is invalid under this part shall be surrendered to the APHIS, REAC Sector Supervisor. If the license cannot be found, the licensee shall provide a written statement so stating to the APHIS, REAC Sector Supervisor.

§ 2.6 Annual license fees.

(a) In addition to the application fee of $10 required to be paid upon the application for a license, license renewal, or changed class of license under § 2.1, each licensee shall submit to the APHIS, REAC Sector Supervisor the annual license fee prescribed in this section. Paragraph (b) of this section indicates the method used to calculate the appropriate fee. The amount of the fee is determined from Table 1 or 2 in paragraph (c) of this section.

(b)(1) Class "A" license. The annual license renewal fee for a Class "A" dealer shall be based on 50 percent of the total gross amount, expressed in dollars, derived from the sale of animals to research facilities, dealers, exhibitors, retail pet stores, and persons for use as pets, directly or through an auction sale, by the dealer or applicant during his or her preceding business year (calendar or fiscal) in the case of a person who operated during such a year. If animals are leased, the lessor shall pay a fee based on 50 percent of any compensation received from the leased animals and the lessee shall pay a fee based upon the net compensation received from the leased animals, as indicated for dealers in Table 1 in paragraph (c) of this section.

(2) Class "B" license. The annual license renewal fee for a Class "B" dealer shall be established by calculating the total amount received from the sale of animals to research facilities, dealers, exhibitors, retail pet stores, and persons for use as pets, directly or through an auction sale, during the preceding business year (calendar or fiscal) less the amount paid for the animals by the dealer or applicant. This net difference, exclusive of other costs, shall be the figure used to determine the license fee of a Class "B" dealer. If animals are leased, the lessor and lessee shall each pay a fee based on the net compensation received from the leased animals calculated from Table 1 in paragraph (c) of this section.

(3) The annual license renewal fee for a broker or operator of an auction sale shall be that of a class "B" dealer and shall be based on the total gross amount, expressed in dollars, derived from commissions or fees charged for the sale of animals, or for negotiating the sale of animals, by brokers or by the operator of an auction sale, to research facilities, dealers, exhibitors, retail pet stores, and persons for use as pets, during the preceding business year (calendar or fiscal).

(4) In the case of a new applicant for a license as a dealer, broker or operator of an auction sale who did not operate during a preceding business year, the annual license fee will be based on the anticipated yearly dollar amount of business, as provided in paragraphs (b)(1), (2), and (3) of this section, derived from the sale of animals to research facilities, dealers, exhibitors, retail pet stores, and persons for use as pets, directly or through an auction sale.

(5) The amount of the annual fee to be paid upon application for a class "C" license as an exhibitor under this section shall be based on the number of

animals which the exhibitor owned, held, or exhibited at the time the application is signed and dated or during the previous year, whichever is greater, and will be the amount listed in Table 2 in paragraph (c) of this section. Animals which are leased shall be included in the number of animals being held by both the lessor and the lessee when calculating the annual fee. An exhibitor shall pay his or her annual license fee on or before the expiration date of the license and the fee shall be based on the number of animals which the exhibitor is holding or has held during the year (both owned and leased).

(c) The license fee shall be computed in accordance with the following tables:

TABLE 1.—DEALERS, BROKERS AND OPERATORS OF AN AUCTION SALE CLASS "A" AND "B" LICENSE

Over	But Not Over	Fee
$0	$500	$30
500	2,000	60
2,000	10,000	120
10,000	25,000	225
25,000	50,000	350
50,000	100,000	475
100,000		750

TABLE 2.—EXHIBITORS—CLASS "C" LICENSE

Number of Animals	Fee
1 to 5	$30
6 to 25	75
26 to 50	175
51 to 500	225
501 and up	300

(d) If a person meets the licensing requirements for more than one class of license, he shall be required to obtain a license and pay the fee for the type business which is predominant for his operation, as determined by the Secretary.

(e) In any situation in which a licensee shall have demonstrated in writing to the satisfaction of the Secretary that he or she has good reason to believe that the dollar amount of his or her business for the forthcoming business year will be less than the previous business year, then his or her estimated dollar amount of business shall be used for computing the license fee for the forthcoming business year: *Provided, however,* That if the dollar amount upon which the license fee is based for that year does in fact exceed the amount estimated, the difference in amount of the fee paid and that which was due under paragraphs (b) and (c) of this section based upon the actual dollar business upon which the license fee is based, shall be payable in addition to the required annual license fee for the next subsequent year, on the anniversary date of his or her license as prescribed in this section.

§ 2.7 Annual report by licensees.

(a) Each year, within 30 days prior to the expiration date of his or her license, a licensee shall file with the APHIS, REAC Sector Supervisor an application for license renewal and annual report upon a form which the APHIS, REAC Sector Supervisor will furnish to him or her upon request.

(b) A person licensed as a dealer shall set forth in his or her license renewal application and annual report the dollar amount of business, from the sale of animals, upon which the license fee is based, directly or through an auction sale, to research facilities, dealers, exhibitors, retail pet stores, and persons for use as pets, by the licensee during the preceding business year (calendar or fiscal), and any other information as may be required thereon.

(c) A licensed dealer who operates as a broker or an operator of an auction sale shall set forth in his or her license renewal application and annual report the total gross amount, expressed in dollars, derived from commissions or fees charged for the sale of animals by the licensee to research facilities, dealers, exhibitors, retail pet stores, and persons for use as pets, during the preceding business year (calendar or fiscal), and any other information as may be required thereon.

(d) A person licensed as an exhibitor shall set forth in his or her license renewal application and annual report the number of animals owned, held, or exhibited by him or her, including those which are leased, during the previous year or at the time he signs and dates the report, whichever is greater.

§ 2.8 Notification of change of name, address, control, or ownership of business.

A licensee shall promptly notify the APHIS, REAC Sector Supervisor by certified mail of any change in the name, address, management, or substantial control or ownership of his business or operation, or of any additional sites, within 10 days of any change

§ 2.9 Officers, agents, and employees of licensees whose licenses have been suspended or revoked.

Any person who has been or is an officer, agent, or employee of a licensee whose license has been suspended or revoked and who was responsible for or participated in the violation upon which the order of suspension or revocation was based will not be licensed within the period during which the order of suspension or revocation is in effect.

§ 2.10 Licensees whose licenses have been suspended or revoked.

(a) Any person whose license has been suspended for any reason shall not be licensed in his or her own name or in any other manner within the period during which the order of suspension is in effect. No partnership, firm, corporation, or other legal entity in which any such person has a substantial interest, financial or otherwise, will be licensed during that period. Any person whose license has been suspended for any reason may apply to the APHIS, REAC Sector Supervisor, in writing, for reinstatement of his or her license.

(b) Any person whose license has been revoked shall not be licensed in his or her own name or in any other manner; nor will any partnership, firm, corporation, or other legal entity in which any such person has a substantial interest, financial or otherwise, be licensed.

(c) Any person whose license has been suspended or revoked shall not buy, sell, transport, exhibit, or deliver for transportation, any animal during the period of suspension or revocation.

§ 2.11 Denial of initial license application.

(a) A license will not be issued to any applicant who:

(1) Has not complied with the raquirements of §§ 2.1, 2.2, 2.3, and 2.4 and has not paid the fees indicated in § 2.6;

(2) Is not in compliance with any of the regulations or standards in this subchapter;

(3) Has had a license revoked or whose license is suspended, as set forth in § 2.10;

(4) Has been fined, sentenced to jail, or pled nolo contendere (no contest) under State or local cruelty to animal laws within 1 year of application, except that if no penalty is imposed as a result of the plea of nolo contendere the applicant may reapply immediately; or

(5) Has made any false or fraudulent statements, or provided any false or fraudulent records to the Department.

(b) An applicant whose license application has been denied may request a hearing in accordance with the applicable rules of practice for the purpose of showing why the application for license should not be denied. The license denial shall remain in effect until the final legal decision has been rendered. Should the license denial be upheld, the applicant may again apply

for a license 1 year from the date of the final order denying the application.

(c) No partnership, firm, corporation, or other legal entity in which a person whose license application has been denied has a substantial interest, financial or otherwise, will be licensed within 1 year of the license denial.

Subpart B—Registration

§ 2.25 Requirements and procedures.

(a) Each carrier and intermediate handler, and each exhibitor not required to be licensed under section 3 of the Act and the regulations of this subchapter, shall register with the Secretary by completing and filing a properly executed form which will be furnished, upon request, by the APHIS, REAC Sector Supervisor. The registration form shall be filed with the APHIS, REAC Sector Supervisor for the State in which the registrant has his or her principal place of business, and shall be updated every 3 years by the completion and filing of a new registration form which will be provided by the APHIS, REAC Sector Supervisor.

(b) A subsidiary of a business corporation, rather than the parent corporation, will be registered as an exhibitor unless the subsidiary is under such direct control of the parent corporation that the Secretary determines that it is necessary that the parent corporation be registered to effectuate the purposes of the Act.

§ 2.26 Acknowledgment of regulations and standards.

APHIS will supply a copy of the regulations and standards in this subchapter with each registration form. The registrant shall acknowledge receipt of and shall agree to comply with the regulations and standards by signing a form provided for this purpose by APHIS, and by filing it with the APHIS, REAC Sector Supervisor.

§ 2.27 Notification of change of operation.

(a) A registrant shall notify the APHIS, REAC Sector Supervisor by certified mail of any change in the name, address, or ownership, or other change in operations affecting its status as an exhibitor, carrier, or intermediate handler, within 10 days after making such change.

(b)(1) A registrant which has not used, handled, or transported animals for a period of at least 2 years may be placed in an inactive status by making a written request to the APHIS, REAC Sector Supervisor A registrant shall notify the APHIS, REAC Sector Supervisor in writing at least 10 days before using, handling, or transporting animals again after being in an inactive status.

(2) A registrant which goes out of business or which ceases to function as a carrier, intermediate handler, or exhibitor, or which changes its method of operation so that it no longer uses, handles, or transports animals, and which does not plan to use, handle, or transport animals again at any time in the future, may have its registration canceled by making a written request to the APHIS, REAC Sector Supervisor. The former registrant is responsible for reregistering and demonstrating its compliance with the Act and regulations should it start using, handling, or transporting animals at any time after its registration is canceled.

Subpart C—Research Facilities

§ 2.30 Registration.

(a) *Requirements and procedures.* (1) Each research facility other than a Federal research facility, shall register with the Secretary by completing and filing a properly executed form which will be furnished, upon request, by the APHIS, REAC Sector Supervisor. The registration form shall be filed with the APHIS, REAC Sector Supervisor for the State in which the research facility has its principal place of business, and shall be updated every 3 years by the completion and filing of a new registration form which will be provided by the APHIS, REAC Sector Supervisor. Except as provided in paragraph (a)(2) of this section, where a school or department of a university or college uses or intends to use live animals for research, tests, experiments, or teaching, the university or college rather than the school or department will be considered the research facility and will be required to register with the Secretary. An official who has the legal authority to bind the parent organization shall sign the registration form.

(2) In any situation in which a school or department of a university or college demonstrates to the Secretary that it is a separate legal entity and its operations and administration are independent of those of the university or college, the school or department will be registered rather than the university or college.

(3) A subsidiary of a business corporation, rather than the parent corporation, will be registered as a research facility unless the subsidiary is under such direct control of the parent corporation that the Secretary determines that it is necessary that the parent corporation be registered to effectuate the purposes of the Act.

(b) *Acknowledgment of regulations and standards.* APHIS will supply a copy of the regulations and standards in this subchapter with each registration form. The research facility shall acknowledge receipt of and shall agree to comply with the regulations and standards by signing a form provided for this purpose by APHIS, and by filing it with the APHIS, REAC Sector Supervisor.

(c) *Notification of change of operation.* (1) A research facility shall notify the APHIS, REAC Sector Supervisor by certified mail of any change in the name, address, or ownership, or other change in operations affecting its status as a research facility, within 10 days after making such change.

(2) A research facility which has not used, handled, or transported animals for a period of at least 2 years may be placed in an inactive status by making a written request to the APHIS, REAC Sector Supervisor. A research facility shall file an annual report of its status (active or inactive). A research facility shall notify the APHIS, REAC Sector Supervisor in writing at least 10 days before using, handling, or transporting animals again after being in an inactive status.

(3) A research facility which goes out of business or which ceases to function as a research facility, or which changes its method of operation so that it no longer uses, handles, or transports animals, and which does not plan to use, handle, or transport animals at any time in the future, may have its registration canceled by making a written request to the APHIS, REAC Sector Supervisor. The research facility is responsible for reregistering and demonstrating its compliance with the Act and regulations should it start using, handling, or transporting animals at any time after its registration is canceled.

§ 2.31 Institutional Animal Care and Use Committee (IACUC).

(a) The Chief Executive Officer of the research facility shall appoint an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members to assess the research facility's animal program, facilities, and procedures. Except as specifically authorized by law or these regulations, nothing in this part shall be deemed to permit the Committee or IACUC to prescribe methods or set standards for the design, performance, or conduct of actual research or experimentation by a research facility.

(b) IACUC Membership. (1) The members of each Committee shall be

appointed by the Chief Executive Officer of the research facility;

(2) The Committee shall be composed of a Chairman and at least two additional members;

(3) Of the members of the Committee:

(i) At least one shall be a Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program responsibility for activities involving animals at the research facility;

(ii) At least one shall not be affiliated in any way with the facility other than as a member of the Committee, and shall not be a member of the immediate family of a person who is affiliated with the facility. The Secretary intends that such person will provide representation for general community interests in the proper care and treatment of animals;

(4) If the Committee consists of more than three members, not more than three members shall be from the same administrative unit of the facility.

(c) IACUC *Functions*. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall:

(1) Review, at least once every six months, the research facility's program for humane care and use of animals, using title 9, chapter I, subchapter A—Animal Welfare, as a basis for evaluation;

(2) Inspect, at least once every six months, all of the research facility's animal facilities, including animal study areas, using title 9, chapter I, subchapter A-Animal Welfare, as a basis for evaluation; *Provided, however,* That animal areas containing free-living wild animals in their natural habitat need not be included in such inspection;

(3) Prepare reports of its evaluations conducted as required by paragraphs (c)(1) and (2) of this section, and submit the reports to the Institutional Official of the research facility; *Provided, however,* That the IACUC may determine the best means of conducting evaluations of the research facility's programs and facilities; and *Provided, further,* That no Committee member wishing to participate in any evaluation conducted under this subpart may be excluded. The IACUC may use subcommittees composed of at least two Committee members and may invite *ad hoc* consultants to assist in conducting the evaluations, however, the IACUC remains responsible for the evaluations and reports as required by the Act and regulations. The reports shall be reviewed and signed by a majority of the IACUC members and must include any minority views. The reports shall be updated at least once every six months upon completion of the required semiannual evaluations and shall be maintained by the research facility and made available to APHIS and to officials of funding Federal agencies for inspection and copying upon request. The reports must contain a description of the nature and extent of the research facility's adherence to this subchapter, must identify specifically any departures from the provisions of title 9, chapter I, subchapter A—Animal Welfare, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, with reference to Subchapter A, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency. Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the Institutional Official, to APHIS and any Federal agency funding that activity;

(4) Review, and, if warranted, investigate concerns involving the care and use of animals at the research facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees;

(5) Make recommendations to the Institutional Official regarding any aspect of the research facility's animal program, facilities, or personnel training;

(6) Review and approve, require modifications in (to secure approval), or withhold approval of those components of proposed activities related to the care and use of animals, as specified in paragraph (d) of this section;

(7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities; and

(8) Be authorized to suspend an activity involving animals in accordance with the specifications set forth in paragraph (d)(6) of this section.

(d) IACUC review of activities involving animals. (1) In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing; *Provided, however,* That field studies as defined in part 1 of this subchapter are exempt from this requirement. Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements:

(i) Procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals;

(ii) The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources, *e.g.*, the Animal Welfare Information Center, used to determine that alternatives were not available;

(iii) The principal investigator has provided written assurance that the activities do not unnecessarily duplicate previous experiments;

(iv) Procedures that may cause more than momentary or slight pain or distress to the animals will:

(A) Be performed with appropriate sedatives, analgesics or anesthetics, unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator and will continue for only the necessary period of time;

(B) Involve, in their planning, consultation with the attending veterinarian or his or her designee;

(C) Not include the use of paralytics without anesthesia;

(v) Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure;

(vi) The animals' living conditions will be appropriate for their species in accordance with part 3 of this subchapter, and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by the attending veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied;

(vii) Medical care for animals will be available and provided as necessary by a qualified veterinarian;

(viii) Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures;

(ix) Activities that involve surgery include appropriate provision for pre-operative and post-operative care of the animals in accordance with established

veterinary medical and nursing practices. All survival surgery will be performed using aseptic procedures, including surgical gloves, masks, sterile instruments, and aseptic techniques. Major operative procedures on non-rodents will be conducted only in facilities intended for that purpose which shall be operated and maintained under aseptic conditions. Non-major operative procedures and all surgery on rodents do not require a dedicated facility, but must be performed using aseptic procedures. Operative procedures conducted at field sites need not be performed in dedicated facilities, but must be performed using aseptic procedures;

(x) No animal will be used in more than one major operative procedure from which it is allowed to recover, unless:

(A) Justified for scientific reasons by the principal investigator, in writing;

(B) Required as routine veterinary procedure or to protect the health or well-being of the animal as determined by the attending veterinarian; or

(C) In other special circumstances as determined by the Administrator on an individual basis. Written requests and supporting data should be sent to the Administrator, APHIS, USDA, 6505 Belcrest Road, Room 268, Hyattsville, MD 20782;

(xi) Methods of euthanasia used must be in accordance with the definition of the term set forth in 9 CFR part 1, § 1.1 of this subchapter, unless a deviation is justified for scientific reasons, in writing, by the investigator.

(2) Prior to IACUC review, each member of the Committee shall be provided with a list of proposed activities to be reviewed. Written descriptions of all proposed activities that involve the care and use of animals shall be available to all IACUC members, and any member of the IACUC may obtain, upon request, full Committee review of those activities. If full Committee review is not requested, at least one member of the IACUC, designated by the chairman and qualified to conduct the review, shall review those activities, and shall have the authority to approve, require modifications in (to secure approval), or request full Committee review of any of those activities. If full Committee review is requested for a proposed activity, approval of that activity may be granted only after review, at a convened meeting of a quorum of the IACUC, and with the approval vote of a majority of the quorum present. No member may participate in the IACUC review or approval of an activity in which that member has a conflicting interest (e.g., is personally involved in the activity), except to provide information requested by the IACUC, nor may a member who has a conflicting interest contribute to the constitution of a quorum;

(3) The IACUC may invite consultants to assist in the review of complex issues arising out of its review of proposed activities. Consultants may not approve or withhold approval of an activity, and may not vote with the IACUC unless they are also members of the IACUC;

(4) The IACUC shall notify principal investigators and the research facility in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval. If the IACUC decides to withhold approval of an activity, it shall include in its written notification a statement of the reasons for its decision and give the principal investigator an opportunity to respond in person or in writing. The IACUC may reconsider its decision, with documentation in Committee minutes, in light of the information provided by the principal investigator;

(5) The IACUC shall conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, but not less than annually;

(6) The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the description of that activity provided by the principal investigator and approved by the Committee. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present;

(7) If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to APHIS and any Federal agency funding that activity; and

(8) Proposed activities and proposed significant changes in ongoing activities that have been approved by the IACUC may be subject to further appropriate review and approval by officials of the research facility. However, those officials may not approve an activity involving the care and use of animals if it has not been approved by the IACUC.

(e) A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following:

(1) Identification of the species and the approximate number of animals to be used;

(2) A rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used;

(3) A complete description of the proposed use of the animals;

(4) A description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research, including provision for the use of analgesic, anesthetic, and tranquilizing drugs where indicated and appropriate to minimize discomfort and pain to animals; and

(5) A description of any euthanasia method to be used.

§ 2.32 Personnel qualifications.

(a) It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel.

(b) Training and instruction shall be made available, and the qualifications of personnel reviewed, with sufficient frequency to fulfill the research facility's responsibilities under this section and § 2.31.

(c) Training and instruction of personnel must include guidance in at least the following areas:

(1) Humane methods of animal maintenance and experimentation, including:

(i) The basic needs of each species of animal;

(ii) Proper handling and care for the various species of animals used by the facility;

(iii) Proper pre-procedural and post-procedural care of animals; and

(iv) Aseptic surgical methods and procedures;

(2) The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress;

(3) Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility;

(4) Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for

reporting violations of any regulation or standards under the Act;

(5) Utilization of services (e.g., National Agricultural Library, National Library of Medicine) available to provide information:

(i) On appropriate methods of animal care and use;

(ii) On alternatives to the use of live animals in research;

(iii) That could prevent unintended and unnecessary duplication of research involving animals; and

(iv) Regarding the intent and requirements of the Act.

§ 2.33 Attending veterinarian and adequate veterinary care.

(a) Each research facility shall have an attending veterinarian who shall provide adequate veterinary care to its animals in compliance with this section:

(1) Each research facility shall employ an attending veterinarian under formal arrangements. In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility;

(2) Each research facility shall assure that the attending veterinarian has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use; and

(3) The attending veterinarian shall be a voting member of the IACUC; *Provided, however,* That a research facility with more than one Doctor of Veterinary Medicine (DVM) may appoint to the IACUC another DVM with delegated program responsibility for activities involving animals at the research facility.

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:

(1) The availability of appropriate facilities, personnel, equipment, and services to comply with the provisions of this subchapter;

(2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care;

(3) Daily observation of all animals to assess their health and well-being; *Provided, however,* That daily observation of animals may be accomplished by someone other than the attending veterinarian; and *Provided, further,* That a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian;

(4) Guidance to principal investigators and other personnel involved in the care and use of animals regarding handling, immobilization, anesthesia, analgesia, tranquilization, and euthanasia; and

(5) Adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures.

§ 2.35 Recordkeeping requirements.

(a) The research facility shall maintain the following IACUC records:

(1) Minutes of IACUC meetings, including records of attendance, activities of the Committee, and Committee deliberations;

(2) Records of proposed activities involving animals and proposed significant changes in activities involving animals, and whether IACUC approval was given or withheld; and

(3) Records of semiannual IACUC reports and recommendations (including minority views), prepared in accordance with the requirements of § 2.31(c)(3) of this subpart, and forwarded to the Institutional Official.

(b) Every research facility shall make, keep, and maintain records or forms which fully and correctly disclose the following information concerning each live dog or cat purchased or otherwise acquired, owned, held, or otherwise in their possession or under their control, transported, euthanized, sold, or otherwise disposed of by the research facility. The records shall include any offspring born of any animal while in the research facility's possession or under its control:

(1) The name and address of the person from whom a dog or cat was purchased or otherwise acquired, whether or not the person is required to be licensed or registered under the Act;

(2) The USDA license or registration number of the person if he or she is licensed or registered under the Act;

(3) The vehicle license number and state, and the driver's license number and state of the person, if he or she is not licensed or registered under the Act;

(4) The date of acquisition of each dog or cat;

(5) The official USDA tag number or tattoo assigned to each dog or cat under § 2.38(g) of this subpart;

(6) A description of each dog or cat which shall include:

(i) The species and breed or type of animal;

(ii) The sex;

(iii) The date of birth or approximate age; and

(iv) The color and any distinctive markings;

(7) Any identification number or mark assigned to each dog or cat by the research facility.

(c) In addition to the information required to be kept and maintained by every research facility concerning each live dog or cat under paragraph (a) of this section, every research facility transporting, selling, or otherwise disposing of any live dog or cat to another person, shall make and maintain records or forms which fully and correctly disclose the following information:

(1) The name and address of the person to whom a live dog or cat is transported, sold, or otherwise disposed of;

(2) The date of transportation, sale, euthanasia, or other disposition of the animal; and

(3) The method of transportation, including the name of the initial carrier or intermediate handler, or if a privately owned vehicle is used to transport the dog or cat, the name of the owner of the privately owned vehicle.

(d)(1) The USDA Interstate and International Certificate of Health Examination for Small Animals (VS Form 18–1) and Record of Dogs and Cats on Hand (VS Form 18–5) are forms which may be used by research facilities to keep and maintain the information required by paragraph (b) of this section.

(2) The USDA Interstate and International Certificate of Health Examination for Small Animals (VS Form 18–1) and Record of Disposition of Dogs and Cats (VS Form 18–6) are forms which may be used by research facilities to keep and maintain the information required by paragraph (c) of this section.

(e) One copy of the record containing the information required by paragraphs (b) and (c) of this section shall accompany each shipment of any live dog or cat sold or otherwise disposed of by a research facility *Provided, however,* That information which indicates the source and date of acquisition of any dog or cat need not appear on the copy of the record accompanying the shipment. One copy of the record containing the information required by paragraphs (b) and (c) of this section shall be retained by the research facility.

(f) All records and reports shall be maintained for at least three years. Records that relate directly to proposed activities and proposed significant changes in ongoing activities reviewed and approved by the IACUC shall be maintained for the duration of the activity and for an additional three years after completion of the activity.

All records shall be available for inspection and copying by authorized APHIS or funding Federal agency representatives at reasonable times. APHIS inspectors will maintain the confidentiality of the information and will not remove the materials from the research facilities' premises unless there has been an alleged violation, they are needed to investigate a possible violation, or for other enforcement purposes. Release of any such materials, including reports, summaries, and photographs that contain trade secrets or commercial or financial information that is privileged or confidential will be governed by applicable sections of the Freedom of Information Act. Whenever the Administrator notifies a research facility in writing that specified records shall be retained pending completion of an investigation or proceeding under the Act, the research facility shall hold those records until their disposition is authorized in writing by the Administrator.

§ 2.36 Annual report.

(a) The reporting facility shall be that segment of the research facility, or that department, agency, or instrumentality of the United States, that uses or intends to use live animals in research, tests, experiments, or for teaching. Each reporting facility shall submit an annual report to the APHIS, REAC Sector Supervisor for the State where the facility is located on or before December 1 of each calendar year. The report shall be signed and certified by the CEO or Institutional Official, and shall cover the previous Federal fiscal year.

(b) The annual report shall:

(1) Assure that professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by the research facility;

(2) Assure that each principal investigator has considered alternatives to painful procedures;

(3) Assure that the facility is adhering to the standards and regulations under the Act, and that it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the IACUC. A summary of all such exceptions must be attached to the facility's annual report. In addition to identifying the IACUC-approved exceptions, this summary must include a brief explanation of the exceptions, as well as the species and number of animals affected;

(4) State the location of all facilities where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes;

(5) State the common names and the numbers of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. Routine procedures (e.g., injections, tattooing, blood sampling) should be reported with this group;

(6) State the common names and the numbers of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used;

(7) State the common names and the numbers of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used shall be attached to the annual report;

(8) State the common names and the numbers of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.

§ 2.37 Federal research facilities.

Each Federal research facility shall establish an Institutional Animal Care and Use Committee which shall have the same composition, duties, and responsibilities required of nonfederal research facilities by § 2.31 with the following exceptions:

(a) The Committee shall report deficiencies to the head of the Federal agency conducting the research rather than to APHIS; and

(b) The head of the Federal agency conducting the research shall be responsible for all corrective action to be taken at the facility and for the granting of all exceptions to inspection protocol.

§ 2.38 Miscellaneous.

(a) *Information as to business: furnishing of same by research facilities.* Each research facility shall furnish to any APHIS official any information concerning the business of the research facility which the APHIS official may request in connection with the enforcement of the provisions of the Act, the regulations, and the standards in this subchapter. The information shall be furnished within a reasonable time and as may be specified in the request for information.

(b) *Access and inspection of records and property.* (1) Each research facility shall, during business hours, allow APHIS officials:

(i) To enter its place of business;

(ii) To examine records required to be kept by the Act and the regulations in this part;

(iii) To make copies of the records;

(iv) To inspect the facilities, property, and animals, as the APHIS officials consider necessary to enforce the provisions of the Act, the regulations, and the standards in this subchapter; and

(v) To document, by the taking of photographs and other means, conditions and areas of noncompliance.

(2) The use of a room, table or other facilities necessary for the proper examination of the records and for inspection of the property or animals shall be extended to APHIS officials by the research facility.

(c) *Publication of names of research facilities subject to the provisions of this part.* APHIS will publish lists of research facilities registered in accordance with the provisions of this subpart in the Federal Register. The lists may be obtained upon request from the APHIS, REAC Sector Supervisor.

(d) *Inspection for missing animals.* Each research facility shall allow, upon request and during business hours, police or officers of other law enforcement agencies with general law enforcement authority (not those agencies whose duties are limited to enforcement of local animal regulations) to enter its place of business to inspect animals and records for the purpose of seeking animals that are missing, under the following conditions:

(1) The police or other law officer shall furnish to the research facility a written description of the missing animal and the name and address of its owner before making a search;

(2) The police or other law officer shall abide by all security measures required by the research facility to prevent the spread of disease, including the use of sterile clothing, footwear, and masks where required, or to prevent the escape of an animal.

(e) *Confiscation and destruction of animals.* (1) If an animal being held by a research facility is not being used to carry out research, testing, or

experimentation, and is found by an APHIS official to be suffering as a result of the failure of the research facility to comply with any provision of the regulations or the standards set forth in this subchapter, the APHIS official shall make a reasonable effort to notify ths research facility of the condition of the animal(s) and request that the condition be corrected and that adequate care be given to alleviate the animal's suffering or distress, or that the animal(s) be destroyed by euthanasia. In the event that the research facility refuses to comply with this request, the APHIS official may confiscate the animal(s) for care, treatment, or disposal as indicated in paragraph (e)(2) of this section, if, in the opinion of the Administrator, the circumstances indicate the animal's health is in danger.

(2) In the event that the APHIS official is unable to locate or notify the research facility as required in this section, the APHIS official shall contact a local police or other law officer to accompany him or her to the premises and shall provide for adequate care when necessary to alleviate the animal's suffering. If, in the opinion of the Administrator, the condition of the animal(s) cannot be corrected by this temporary care, the APHIS official shall confiscate the animal(s).

(3) Confiscated animals may be placed, by sale or donation, with other registrants or licensees that comply with the standards and regulations and can provide proper care, or they may be euthanized. The research facility from which the animals were confiscated shall bear all costs incurred in performing the placement or euthanasia activities authorized by this section.

(f) *Handling.* (1) Handling of all animals shall be done as expeditiously and carefully as possibls in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort.

(2)(i) Physical abuse shall not be used to train, work, or otherwise handle animals.

(ii) Deprivation of food or water shall not be used to train, work, or otherwise handle animals; *Provided, however:* That the short-term withholding of food or water from animals, when specified in an IACUC-approved activity that includes a description of monitoring procedures, is allowed by these regulations.

(g) *Identification of dogs and cats.* (1) All live dogs or cats, including those from any exempt source, delivered for transportation, transported, purchased or otherwise acquired. sold, or disposed of by a research facility, shall be identified at the time of such delivery for transportation, purchase, sale, disposal, or acquisition in one of the following ways:

(i) By the official tag or tattoo which was affixed to the animal at the time it was acquired by the research facility, as required by this section; or

(ii) By a tag, tattoo, or collar, applied to the live dog or cat by the research facility and which individually identifies the dog or cat by number.

(2) All official tag or tattoo numbers shall be correctly listed in the records of purchase, acquisition, disposal, or sale which shall be maintained in accordance with § 2.35.

(3) Unweaned puppies or kittens need not be individually identified while they are maintained as a litter with their dam in the same primary enclosure, provided the dam has been individually identified.

(4) The official tag shall be made of a durable alloy such as brass, bronze, or steel, or of a durable plastic. Aluminum of a sufficient thickness to assure the tag is durable and legible may also be used. The tag may be circular in shape and not less than 1¼ inches in diameter, or oblong and flat in shape and not less than 2 inches by ¾ inch, and riveted to an acceptable collar.

(5) Each tag shall have the following information embossed or stamped on so that it is easily readable:

(i) The letters "USDA";

(ii) Numbers identifying the State and dealer, exhibitor, or research facility (e.g., 39–AB); and

(iii) Numbers identifying the animal (e.g., 82488).

(6) Official tags shall be serially numbered and shall be applied to dogs or cats in the manner set forth in this section in as close to consecutive numerical order as possible. No tag number shall be used to identify more than one animal or shall be reused within a 5-year period.

(7) Research facilities may obtain, at their own expense, official tags from commercial tag manufacturers.[1] At the time the research facility is registered, the Department will assign identification letters and numbers to be used on the official tags.

(8) Each research facility shall be held accountable for all official tags acquired. In the event an official tag is lost from a dog or cat while in the possession of a research facility, the facility shall make a diligent effort to locate and reapply the tag to the proper animal. If the lost tag is not located, the research facility shall affix another official tag to the animal in the manner prescribed in this section and record the tag number on the official records.

(9) When a dog or cat wearing or identified by an official tag arrives at a research facility, the facility may continue to use that tag to identify the dog or cat or the tag may be replaced as indicated in paragraph (g)(1) of this section. All tags removed by a research facility shall be retained and disposed of as indicated in this section.

(10) Where a dog or cat to which is affixed or which is identified by an official tag is euthanized, or dies from other causes, the research facility shall remove and retain the tag for the required period, as set forth in paragraph (g)(11) of this section.

(11) All official tags removed and retained by a research facility shall be held until called for by an APHIS official or for a period of 1 year.

(12) When official tags are removed from animals for disposal, the tags must be disposed of so as to preclude their reuse for animal identification. No animal identification number shall be used within any 5-year period following its previous use.

(h) *Health certification.* (1) No research facility, including a Federal research facility, shall deliver to any intermediate handler or carrier for transportation, in commerce, or shall transport in commerce any dog, cat, or nonhuman primate unless the dog, cat, or nonhuman primate is accompanied by a health certificate executed and issued by a licensed veterinarian. The health certificate shall state that:

(i) The licensed vetarinarian inspected the dog, cat, or nonhuman primate on a specified date which shall not be more than 10 days prior to the delivery of the dog, cat, or nonhuman primate for transportation; and

(ii) When so inspected, the dog, cat, or nonhuman primate appeared to the licensed veterinarian to be free of any infectious disease or physical abnormality which would endanger the animal(s) or other animals or endangar public health.

(2) The Secretary may provide exceptions to the health certification requirement on an individual basis for animals shipped to a research facility for purposes of research, testing, or experimentation when the research facility requires animals not eligible for certification. Requests should be addressed to the Administrator, APHIS,

[1] A list of the commercial manufacturers who produce these tags and are known to the Department may be obtained from the APHIS, REAC Sector Supervisor. Any manufacturer who desires to be included in the list should notify the Administrator.

USDA, Room 268, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782.

(3) The U.S. Interstate and International Certificate of Health Examination for Small Animals (VS Form 18–1) may be used for health certification by a licensed veterinarian as required by this section.

(i) *Holding of animals.* If any research facility obtains prior approval of the APHIS, REAC Sector Supervisor, it may arrange to have another person hold animals: *Provided,* That:

(1) The other person agrees, in writing, to comply with the regulations in this part and the standards in part 3 of this subchapter, and to allow inspection of the premises by an APHIS official during business hours;

(2) The animals remain under the total control and responsibility of the research facility; and

(3) The Institutional Official agrees, in writing, that the other person or premises is a recognized animal site under its research facility registration. Veterinary Services Form 18–9 shall be used for approval.

(j) *Holding period.* Research facilities that obtain dogs and cats from sources other than dealers, exhibitors, and exempt persons shall hold the animals for 5 full days, not including the day of acquisition, after acquiring the animal, excluding time in transit, before they may be used by the facility. Research facilities shall comply with the identification of animals requirements set forth in § 2.38(g) during this period.

(k) *Compliance with standards and prohibitions.* (1) Each research facility shall comply in all respects with the regulations set forth in subpart C of this part and the standards set forth in part 3 of this subchapter for the humane handling, care, treatment, housing, and transportation of animals; *Provided, however,* That exceptions to the standards in part 3 and the provisions of subpart C of this part may be made only when such exceptions are specified and justified in the proposal to conduct the activity and are approved by the IACUC.

(2) No person shall obtain live random source dogs or cats by use of false pretenses, misrepresentation, or deception.

(3) No person shall acquire, buy, sell, exhibit, use for research, transport, or offer for transportation, any stolen animal.

Subpart D—Attending Veterinarian and Adequate Veterinary Care

§ 2.40 Attending veterinarian and adequate veterinary care (dealers and exhibitors).

(a) Each dealer or exhibitor shall have an attending veterinarian who shall provide adequate veterinary care to its animals in compliance with this section.

(1) Each dealer and exhibitor shall employ an attending veterinarian under formal arrangements. In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the premises of the dealer or exhibitor; and

(2) Each dealer and exhibitor shall assure that the attending veterinarian has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

(b) Each dealer or exhibitor shall establish and maintain programs of adequate veterinary care that include:

(1) The availability of appropriate facilities, personnel, equipment, and services to comply with the provisions of this subchapter;

(2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care;

(3) Daily observation of all animals to assess their health and well-being; *Provided, however,* That daily observation of animals may be accomplished by someone other than the attending veterinarian; and *Provided, further,* That a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian;

(4) Adequate guidance to personnel involved in the care and use of animals regarding handling, immobilization, anesthesia, analgesia, tranquilization, and euthanasia; and

(5) Adequate pre-procedural and post-procedural care in accordance with established veterinary medical and nursing procedures.

Subpart E—Identification of Animals

§ 2.50 Time and method of identification.

(a) A class "A" dealer (breeder) shall identify all live dogs and cats on the premises as follows:

(1) All live dogs and cats held on the premises, purchased, or otherwise acquired, sold or otherwise disposed of, or removed from the premises for delivery to a research facility or exhibitor or to another dealer, or for sale, through an auction sale or to any person for use as a pet, shall be identified by an official tag of the type described in § 2.51 affixed to the animal's neck by means of a collar made of material generally considered acceptable to pet owners as a means of identifying their pet dogs or cats [2], or shall be identified by a distinctive and legible tattoo marking acceptable to and approved by the Administrator.

(2) Live puppies or kittens, less than 16 weeks of age, shall be identified by:

(i) An official tag as described in § 2.51;

(ii) A distinctive and legible tattoo marking approved by the Administrator; or

(iii) A plastic-type collar acceptable to the Administrator which has legibly placed thereon the information required for an official tag pursuant to § 2.51.

(b) A class "B" dealer shall identify all live dogs and cats under his or her control or on his or her premises as follows:

(1) When live dogs or cats are held, purchased, or otherwise acquired, they shall be immediately identified:

(i) By affixing to the animal's neck an official tag as set forth in § 2.51 by means of a collar made of material generally acceptable to pet owners as a means of identifying their pet dogs or cats [2]; or

(ii) By a distinctive and legible tattoo marking approved by the Administrator.

(2) If any live dog or cat is already identified by an official tag or tattoo which has been applied by another dealer or exhibitor, the dealer or exhibitor who purchases or otherwise acquires the animal may continue identifying the dog or cat by the previous identification number, or may replace the previous tag with his own official tag or approved tattoo. In either case, the class B dealer or class C exhibitor shall correctly list all old and new official tag numbers or tattoos in his or her records of purchase which shall be maintained in accordance with §§ 2.75 and 2.77. Any new official tag or tattoo number shall be used on all

[2] In general, well fitted collars made of leather or plastic will be acceptable under this provision. The use of certain types of chains presently used by some dealers may also be deemed acceptable. APHIS will determine the acceptability of a material proposed for usage as collars from the standpoint of humane considerations on an individual basis in consultation with the dealer or exhibitor involved. The use of materials such as wire, elastic, or sharp metal that might cause discomfort or injury to the dogs or cats is not acceptable.

[3] See footnote 2 in § 2.50(a)(1).

records of any subsequent sales by the dealer or exhibitor, of any dog or cat.

(3) Live puppies or kittens less than 16 weeks of age, shall be identified by:

(i) An official tag as described in § 2.51;

(ii) A distinctive and legible tattoo marking approved by the Administrator; or

(iii) A plastic-type collar acceptable to the Administrator which has legibly placed thereon the information required for an official tag pursuant to § 2.51.

(4) When any dealer has made a reasonable effort to affix an official tag to a cat, as set forth in paragraphs (a) and (b) of this section, and has been unable to do so, or when the cat exhibits serious distress from the attachment of a collar and tag, the dealer shall attach the collar and tag to the door of the primary enclosure containing the cat and take measures adequate to maintain the identity of the cat in relation to the tag. Each primary enclosure *shall* contain no more than one weaned cat without an affixed collar and official tag, unless the cats are identified by a distinctive and legible tattoo or plastic-type collar approved by the Administrator.

(c) A class "C" exhibitor shall identify all live dogs and cats under his or her control or on his or her premises, whether held, purchased, or otherwise acquired:

(1) As set forth in paragraph (b)(1) or (b)(3) of this section, or

(2) By identifying each dog or cat with:

(i) An official USDA sequentially numbered tag that is kept on the door of the animal's cage or run;

(ii) A record book containing each animal's tag number, a written description of each animal, the data required by § 2.75(a), and a clear photograph of each animal; and

(iii) A duplicate tag that accompanies each dog or cat whenever it leaves the compound or premises.

(d) Unweaned puppies or kittens need not be individually identified as required by paragraphs (a) and (b) of this section while they are maintained as a litter with their dam in the same primary enclosure, provided the dam has been individually identified.

(e)(1) All animals, except dogs and cats, delivered for transportation, transported, purchased, sold, or otherwise acquired or disposed of by any dealer or exhibitor shall be identified by the dealer or exhibitor at the time of delivery for transportation, purchase, sale, acquisition or disposal, as provided for in this paragraph and in records maintained as required in §§ 2.75 and 2.77.

(2) When one or more animals, other than dogs or cats, are confined in a primary enclosure, the animal(s) shall be identified by:

(i) A label attached to the primary enclosure which shall bear a description of the animals in the primary enclosure, including:

(A) The number of animals;

(B) The species of the animals;

(C) Any distinctive physical features of the animals; and

(D) Any identifying marks, tattoos, or tags attached to the animals;

(ii) Marking the primary enclosure with a painted or stenciled number which shall be recorded in the records of the dealer or exhibitor together with:

(A) A description of the animal(s);

(B) The species of the animal(s); and

(C) Any distinctive physical features of the animal(s); or

(iii) A tag or tattoo applied to each animal in the primary enclosure by the dealer or exhibitor which individually identifies each animal by description or number.

(3) When any animal, other than a dog or cat, is not confined in a primary enclosure, it shall be identified on a record, as required by § 2.75, which shall accompany the animal at the time it is delivered for transportation, transported, purchased, or sold, and shall be kept and maintained by the dealer or exhibitor as part of his or her records.

§ 2.51 Form of official tag.

(a) The official tag shall be made of a durable alloy such as brass, bronze, or steel, or of a durable plastic. Aluminum of a sufficient thickness to assure the tag is durable and legible may also be used. The tag shall be one of the following shapes:

(1) Circular in shape and not less than 1¼ inches in diameter, or

(2) Oblong and flat in shape, not less than 2 inches by ¾ inch and riveted to an acceptable collar.

(b) Each tag shall have the following information embossed or stamped on so that it is easily readable:

(1) The letters "USDA";

(2) Numbers identifying the State and dealer, exhibitor, or research facility (*e.g.*, 39–AB); and

(3) Numbers identifying the animal (*e.g.*, 82488).

(c) Official tags shall be serially numbered. No individual dealer or exhibitor shall use any identification tag number more than once within a 5-year period.

§ 2.52 How to obtain tags.

Dealers or exhibitors may obtain, at their own expense, official tags from commercial tag manufacturers.[4] At the time the dealer or exhibitor is issued a license or is registered, the Department will assign identification letters and numbers and inform them of the identification letters and numbers to be used on the official tags.

§ 2.53 Use of tags.

Official tags obtained by a dealer, exhibitor, or research facility, shall be applied to dogs or cats in the manner set forth in § 2.50 and in as close to consecutive numerical order as possible. No tag number shall be used to identify more than one animal. No number shall be repeated within a 5-year period.

§ 2.54 Lost tags.

Each dealer or exhibitor shall be held accountable for all official tags acquired. In the event an official tag is lost from a dog or cat while in the possession of a dealer or exhibitor, the dealer or exhibitor shall make a diligent effort to locate and reapply the tag to the proper animal. If the lost tag is not located, the dealer or exhibitor shall affix another official tag to the animal in the manner prescribed in § 2.50, and record the tag number on the official records.

§ 2.55 Removal and disposal of tags.

(a) Where a dog or cat to which is affixed or which is identified by an official tag is euthanized, or dies from other causes, the dealer or exhibitor shall remove and retain the tag for the required period, as set forth in paragraph (b) of this section.

(b) All official tags removed and retained by a dealer or exhibitor shall be held until called for by an APHIS official or for a period of 1 year.

(c) When official tags are removed from animals for disposal, the tags must be disposed of so as to preclude their reuse for animal identification. No animal identification number shall be used within any 5-year period following its previous use.

Subpart F—Stolen Animals

§ 2.60 Prohibition on the purchase, sale, use, or transportation of stolen animals.

No person shall buy, sell, exhibit, use for research, transport, or offer for transportation, any stolen animal.

[4] A list of the commercial manufacturers who produce these tags and are known to the Department may be obtained from the APHIS, REAC Sector Supervisor. Any manufacturer who desires to be included in the list should notify the Administrator.

Subpart G—Records

§ 2.75 Records: Dealers and exhibitors.

(a)(1) Each dealer, other than operators of auction sales and brokers to whom animals are consigned, and each exhibitor shall make, keep, and maintain records or forms which fully and correctly disclose the following information concerning each dog or cat purchased or otherwise acquired, owned, held, or otherwise in his or her possession or under his or her control, or which is transported, euthanized, sold, or otherwise disposed of by that dealer or exhibitor. The records shall include any offspring born of any animal while in his or her possession or under his or her control.

(i) The name and address of the person from whom a dog or cat was purchased or otherwise acquired whether or not the person is required to be licensed or registered under the Act;

(ii) The USDA license or registration number of the person if he or she is licensed or registered under the Act;

(iii) The vehicle license number and state, and the driver's license number and state of the person, if he or she is not licensed or registered under the Act;

(iv) The name and address of the person to whom a dog or cat was sold or given and that person's license or registration number if he or she is licensed or registered under the Act;

(v) The date a dog or cat was acquired or disposed of, including by euthanasia;

(vi) The official USDA tag number or tattoo assigned to a dog or cat under §§ 2.50 and 2.54;

(vii) A description of each dog or cat which shall include:

(A) The species and breed or type;

(B) The sex;

(C) The date of birth or approximate age; and

(D) The color and any distinctive markings;

(viii) The method of transportation including the name of the initial carrier or intermediate handler or, if a privately owned vehicle is used to transport a dog or cat, the name of the owner of the privately owned vehicle;

(ix) The date and method of disposition of a dog or cat, e.g., sale, death, euthanasia, or donation.

(2) Record of Dogs and Cats on Hand (VS Form 18–5) and Record of Disposition of Dogs and Cats (VS Form 18–6) are forms which may be used by dealers and exhibitors to make, keep, and maintain the information required by paragraph (a)(1) of this section.

(3) The USDA Interstate and International Certificate of Health Examination for Small Animals (VS Form 18–1) may be used by dealers and exhibitors to make, keep, and maintain the information required by paragraph (a)(1) of this section and § 2.79.

(4) One copy of the record containing the information required by paragraph (a)(1) of this section shall accompany each shipment of any dog or cat purchased or otherwise acquired by a dealer or exhibitor. One copy of the record containing the information required by paragraph (a)(1) of this section shall accompany each shipment of any dog or cat sold or otherwise disposed of by a dealer or exhibitor: *Provided, however*, That information which indicates the source and date of acquisition of a dog or cat need not appear on the copy of the record accompanying the shipment. One copy of the record containing the information required by paragraph (a)(1) of this section shall be retained by the dealer or exhibitor.

(b)(1) Every dealer other than operators of auction sales and brokers to whom animals are consigned, and exhibitor shall make, keep, and maintain records or forms which fully and correctly disclose the following information concerning animals other than dogs and cats, purchased or otherwise acquired, owned, held, leased, or otherwise in his or her possession or under his or her control, or which is transported, sold, euthanized, or otherwise disposed of by that dealer or exhibitor. The records shall include any offspring born of any animal while in his or her possession or under his or her control.

(i) The name and address of the person from whom the animals were purchased or otherwise acquired;

(ii) The USDA license or registration number of the person if he or she is licensed or registered under the Act;

(iii) The vehicle license number and state, and the driver's license number and state of the person, if he or she is not licensed or registered under the Act;

(iv) The name and address of the person to whom an animal was sold or given;

(v) The date of purchase, acquisition, sale, or disposal of the animal(s);

(vi) The species of the animal(s); and

(vii) The number of animals in the shipment.

(2) Record of Animals on Hand (other than dogs and cats) (VS Form 18–19) and Record of Acquisition, Disposition, or Transport of Animals (other than dogs and cats) (VS Form 18–20) are forms which may be used by dealers and exhibitors to keep and maintain the information required by paragraph (b)(1) of this section concerning animals other than dogs and cats except as provided in § 2.79.

(3) One copy of the record containing the information required by paragraph (b)(1) of this section shall accompany each shipment of any animal(s) other than a dog or cat purchased or otherwise acquired by a dealer or exhibitor. One copy of the record containing the information required by paragraph (b)(1) of this section shall accompany each shipment of any animal other than a dog or cat sold or otherwise disposed of by a dealer or exhibitor; *Provided, however*, That information which indicates the source and date of acquisition of any animal other than a dog or cat need not appear on the copy of the record accompanying the shipment. The dealer or exhibitor shall retain one copy of the record containing the information required by paragraph (b)(1) of this section.

§ 2.76 Records: Operators of auction sales and brokers.

(a) Every operator of an auction sale or broker shall make, keep, and maintain records or forms which fully and correctly disclose the following information concerning each animal consigned for auction or sold, whether or not a fee or commission is charged:

(1) The name and address of the person who owned or consigned the animal(s) for sale;

(2) The name and address of the buyer or consignee who received the animal;

(3) The USDA license or registration number of the person(s) selling, consigning, buying, or receiving the animals if he or she is licensed or registered under the Act;

(4) The vehicle license number and state, and the driver's license number and state of the person, if he or she is not licensed or registered under the Act;

(5) The date of the consignment;

(6) The official USDA tag number or tattoo assigned to the animal under §§ 2.50 and 2.54;

(7) A description of the animal which shall include:

(i) The species and breed or type of animal;

(ii) The sex of the animal; and

(iii) The date of birth or approximate age; and

(iv) The color and any distinctive markings;

(8) The auction sales number or records number assigned to the animal.

(b) One copy of the record containing the information required by paragraph (a) of this section shall be given to the consignor of each animal, one copy of the record shall be given to the purchaser of each animal: *Provided, however*, That information which indicates the source and date of

consignment of any animal need not appear on the copy of the record given the purchaser of any animal. One copy of the record containing the information required by paragraph (a) of this section shall be retained by the operator of such auction sale, or broker, for each animal sold by the auction sale or broker.

§ 2.77 Records: Carriers and intermediate handlers.

(a) In connection with all live animals accepted for shipment on a C.O.D. basis or other arrangement or practice under which the cost of an animal or the transportation of an animal is to be paid and collected upon delivery of the animal to the consignee, the accepting carrier or intermediate handler, if any, shall keep and maintain a copy of the consignor's written guarantee for the payment of transportation charged for any animal not claimed as provided in § 2.80, including, where necessary, both the return transportation charges and an amount sufficient to reimburse the carrier for out-of-pocket expenses incurred for the care, feeding, and storage of the animal. The carrier or intermediate handler at destination shall also keep and maintain a copy of the shipping document containing the time, date, and method of each attempted notification and the final notification to the consignee and the name of the person notifying the consignee, as provided in § 2.80.

(b) In connection with all live dogs, cats, or nonhuman primates delivered for transportation, in commerce, to any carrier or intermediate handler, by any dealer, research facility, exhibitor, operator of an auction sale, broker, or department, agency or instrumentality of the United States or of any state or local government, the accepting carrier or intermediate handler shall keep and maintain a copy of the health certification completed as required by § 2.79, tendered with each live dog, cat, or nonhuman primate.

§ 2.78 Health certification and identification.

(a) No dealer, exhibitor, operator of an auction sale, broker, or department, agency, or instrumentality of the United States or of any State or local government shall deliver to any intermediate handler or carrier for transportation, in commerce, or shall transport in commerce any dog, cat, or nonhuman primate unless the dog, cat, or nonhuman primate is accompanied by a health certificate executed and issued by a licensed veterinarian. The health certificate shall state that:

(1) The licensed veterinarian inspected the dog, cat, or nonhuman primate on a specified date which shall not be more than 10 days prior to the delivery of the dog, cat, or nonhuman primate for transportation; and

(2) when so inspected, the dog, cat, or nonhuman primate appeared to the licensed veterinarian to be free of any infectious disease or physical abnormality which would endanger the animal(s) or other animals or endanger public health.

(b) The Secretary may provide exceptions to the health certification requirement on an individual basis for animals shipped to a research facility for purposes of research, testing, or experimentation when the research facility requires animals not eligible for certification. Requests should be addressed to the Administrator, APHIS, USDA, Room 206, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782.

(c) No intermediate handler or carrier to whom any live dog, cat, or nonhuman primate is delivered for transportation by any dealer, research facility, exhibitor, broker, operator of an auction sale, or department, agency, or instrumentality of the United States or any State or local government shall receive a live dog, cat, or nonhuman primate for transportation, in commerce, unless and until it is accompanied by a health certificate issued by a licensed veterinarian in accordance with paragraph (a) of this section, or an exemption issued by the Secretary in accordance with paragraph (b) of this section.

(d) The U.S. Interstate and International Certificate of Health Examination for Small Animals (VS Form 18-1) may be used for health certification by a licensed veterinarian as required by this section.

§ 2.79 C.O.D. shipments.

(a) No carrier or intermediate handler shall accept any animal for transportation, in commerce, upon any C.O.D. or other basis where any money is to be paid and collected upon delivery of the animal to the consignee, unless the consignor guarantees in writing the payment of all transportation, including any return transportation, if the shipment is unclaimed or the consignee cannot be notified in accordance with paragraphs (b) and (c) of this section, including reimbursing the carrier or intermediate handler for all out-of-pocket expenses incurred for the care, feeding, and storage or housing of the animal.

(b) Any carrier or intermediate handler receiving an animal at a destination on a C.O.D. or other basis any money is to be paid and collected upon delivery of the animal to the consignee shall attempt to notify the consignee at least once every 6 hours for a period of 24 hours after arrival of the animal at the animal holding area of the terminal cargo facility. The carrier or intermediate handler shall record the time, date, and method of each attempted notification and the final notification to the consignee, and the name of the person notifying the consignee, on the shipping document and on the copy of the shipping document accompanying the C.O.D. shipment. If the consignee cannot be notified of the C.O.D. shipment within 24 hours after its arrival, the carrier or intermediate handler shall return the animal to the consignor, or to whomever the consignor has designated, on the next practical available transportation, in accordance with the written agreement required in paragraph (a) of this section and shall notify the consignor. Any carrier or intermediate handler which has notified a consignee of the arrival of a C.O.D. or other shipment of an animal, where any money is to be paid and collected upon delivery of the animal to the consignee, which is not claimed by the consignee within 48 hours from the time of notification, shall return the animal to the consignor, or to whomever the consignor has designated, on the next practical available transportation, in accordance with the written agreement required in paragraph (a) of this section and shall notify the consignor.

(c) It is the responsibility of any carrier or intermediate handler to hold, feed, and care for any animal accepted for transportation, in commerce, under a C.O.D. or other arrangement where any money is to be paid and collected upon delivery of the animal until the consignee accepts shipment at destination or until returned to the consignor or his or her designee should the consignee fail to accept delivery of the animal or if the consignee could not be notified as prescribed in paragraph (b) of this section.

(d) Nothing in this section shall be construed as prohibiting any carrier or intermediate handler from requiring any guarantee in addition to that required in paragraph (a) of this section for the payment of the cost of any transportation or out-of-pocket or other incidental expenses incurred in the transportation of any animal.

§ 2.80 Records, disposition.

(a) No dealer, exhibitor, broker, operator of an auction sale, carrier, or intermediate handler shall, for a period of 1 year, destroy or dispose of, without the consent in writing of the Administrator, any books, records,

documents, or other papers required to be kept and maintained under this part.

(b) Unless otherwise specified, the records required to be kept and maintained under this part shall be held for 1 year after an animal is euthanized or disposed of and for any period in excess of one year as necessary to comply with any applicable Federal, State, or local law. Whenever the Administrator notifies a dealer, exhibitor, broker, operator of an auction sale, carrier, or intermediate handler in writing that specified records shall be retained pending completion of an investigation or proceeding under the Act, the dealer, exhibitor, broker, operator of an auction sale, carrier, or intermediate handler shall hold those records until their disposition is authorized by the Administrator.

Subpart H—Compliance With Standards and Holding Period

§ 2.100 Compliance with standards.

(a) Each dealer, exhibitor, operator of an auction sale, and intermediate handler shall comply in all respects with the regulations set forth in part 2 and the standards set forth in part 3 of this subchapter for the humane handling, care, treatment, housing, and transportation of animals.

(b) Each carrier shall comply in all respects with the regulations in part 2 and the standards in part 3 of this subchapter setting forth the conditions and requirements for the humane transportation of animals in commerce and their handling, care, and treatment in connection therewith.

§ 2.101 Holding period.

(a) Any live dog or cat acquired by a dealer [8] or exhibitor shall be held by him or her, under his or her supervision and control, for a period of not less than 5 full days, not including the day of acquisition, after acquiring the animal, excluding time in transit: *Provided, however*:

(1) That any live dog or cat acquired by a dealer or exhibitor from any private or contract animal pound or shelter shall be held by that dealer or exhibitor under his or her supervision and control for a period of not less than 10 full days, not including the day of acquisition, after acquiring the animal, excluding time in transit;

(2) Live dogs or cats which have completed a 5-day holding period with another dealer or exhibitor, or a 10-day holding period with another dealer or exhibitor if obtained from a private or contract shelter or pound, may be sold or otherwise disposed of by subsequent dealers or exhibitors after a minimum holding period of 24 hours by each subsequent dealer or exhibitor excluding time in transit;

(3) Any dog or cat suffering from disease, emaciation, or injury may be destroyed by euthanasia prior to the completion of the holding period required by this section; and

(4) Any live dog or cat, 120 days of age or less, that was obtained from the person that bred and raised such dog or cat, may be exempted from the 5-day holding requirement and may be disposed of by dealers or exhibitors after a minimum holding period of 24 hours, excluding time in transit. Each subsequent dealer or exhibitor must also hold each such dog or cat for a 24-hour period excluding time in transit.

(b) During the period in which any dog or cat is being held as required by this section, the dog or cat shall be unloaded from any means of conveyance in which it was received, for food, water, and rest, and shall be handled, cared for, and treated in accordance with the standards set forth in part 3, subpart A, of this subchapter and § 2.131.

§ 2.102 Holding facility.

(a) If any dealer or exhibitor obtains the prior approval of the APHIS, REAC Sector Supervisor, he may arrange to have another person hold animals for the required period provided for in paragraph (a) of § 2.101: *Provided*, That:

(1) The other person agrees ip writing to comply with the regulations in part 2 and the standards in part 3 of this subchapter and to allow inspection of his premises by an APHIS official during business hours; and

(2) The animals remain under the total control and responsibility of the dealer or exhibitor.

(3) Approval will not be given for a dealer or exhibitor holding a license as set forth in § 2.1 to have animals held for purposes of this section by another licensed dealer or exhibitor. Veterinary Services Form 18–9 shall be used for approval.

(b) If any intermediate handler obtains prior approval of the APHIS, REAC Sector Supervisor, it may arrange to have another person hold animals: *Provided*, That:

(1) The other person agrees in writing to comply with the regulations in part 2 and the standards in part 3 of this subchapter and to allow inspection of the premises by an APHIS official during business hours; and

(2) The animals remain under the total control and responsibility of the research facility or intermediate handler.

Subpart I—Miscellaneous

§ 2.125 Information as to business; furnishing of same by dealers, exhibitors, operators of auction sales, intermediate handlers, and carriers.

Each dealer, exhibitor, operator of an auction sale, intermediate handler, and carrier shall furnish to any APHIS official any information concerning the business of the dealer, exhibitor, operator of an auction sale, intermediate handler or carrier which the APHIS official may request in connection with the enforcement of the provisions of the Act, the regulations and the standards in this subchapter. The information shall be furnished within a reasonable time and as may be specified in the request for information.

§ 2.126 Access and inspection of records and property.

(a) Each dealer, exhibitor, intermediate handler, or carrier, shall, during business hours, allow APHIS officials:

(1) To enter its place of business;

(2) To examine records required to be kept by the Act and the regulations in this part;

(3) To make copies of the records;

(4) To inspect and photograph the facilities, property and animals, as the APHIS officials consider necessary to enforce the provisions of the Act, the regulations and the standards in this subchapter; and

(5) To document, by the taking of photographs and other means, conditions and areas of noncompliance.

(b) The use of a room, table, or other facilities necessary for the proper examination of the records and inspection of the property or animals shall be extended to APHIS officials by the dealer, exhibitor, intermediate handler or carrier.

§ 2.127 Publication of names of persons subject to the provisions of this part.

APHIS will publish lists of persons licensed or registered in accordance with the provisions of this part in the **Federal Register**. The lists may be obtained upon request from the APHIS, REAC Sector Supervisor.

§ 2.128 Inspection for missing animals.

Each dealer, exhibitor, intermediate handler and carrier shall allow, upon request and during business hours, police or officers of other law enforcement agencies with general law

[8] An operator of an auction sale is not considered to have acquired a dog or cat which is sold through the auction sale.

enforcement authority (not those agencies whose duties are limited to enforcement of local animal regulations) to enter his or her place of business to inspect animals and records for the purpose of seeking animals that are missing, under the following conditions:

(a) The police or other law officer shall furnish to the dealer, exhibitor, intermediate handler or carrier a written description of the missing animal and the name and address of its owner before making a search.

(b) The police or other law officer shall abide by all security measures required by the dealer, exhibitor, intermediate handler or carrier to prevent the spread of disease, including the use of sterile clothing, footwear, and masks where required, or to prevent the escape of an animal.

§ 2.129 Confiscation and destruction of animals.

(a) If an animal being held by a dealer, exhibitor, intermediate handler, or by a carrier is found by an APHIS official to be suffering as a result of the failure of the dealer, exhibitor, intermediate handler, or carrier to comply with any provision of the regulations or the standards set forth in this subchapter, the APHIS official shall make a reasonable effort to notify the dealer, exhibitor, intermediate handler, or carrier of the condition of the animal(s) and request that the condition be corrected and that adequate care be given to alleviate the animal's suffering or distress, or that the animal(s) be destroyed by euthanasia. In the event that the dealer, exhibitor, intermediate handler, or carrier refuses to comply with this request, the APHIS official may confiscate the animal(s) for care, treatment, or disposal as indicated in paragraph (b) of this section, if, in the opinion of the Administrator, the circumstances indicate the animal's health is in danger.

(b) In the event that the APHIS official is unable to locate or notify the dealer, exhibitor, intermediate handler, or carrier as required in this section, the APHIS official shall contact a local police or other law officer to accompany him to the premises and shall provide for adequate care when necessary to alleviate the animal's suffering. If in the opinion of the Administrator, the condition of the animal(s) cannot be corrected by this temporary care, the APHIS official shall confiscate the animals.

(c) Confiscated animals may be placed, by sale or donation, with other licensees or registrants which comply with the standards and regulations and can provide proper care, or they may be euthanized. The dealer, exhibitor, intermediate handler, or carrier from whom the animals were confiscated shall bear all costs incurred in performing the placement or euthanasia activities authorized by this section.

§ 2.130 Minimum age requirements.

No dog or cat shall be delivered by any person to any carrier or intermediate handler for transportation, in commerce, or shall be transported in commerce by any person, except to a registered research facility, unless such dog or cat is at least eight (8) weeks of age and has been weaned.

§ 2.131 Handling of animals.

(a)(1) Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort.

(2)(i) Physical abuse shall not be used to train, work, or otherwise handle animals.

(ii) Deprivation of food or water shall not be used to train, work, or otherwise handle animals; *Provided, however,* That the short-term withholding of food or water from animals by exhibitors is allowed by these regulations as long as each of the animals affected receives its full dietary and nutrition requirements each day.

(b)(1) During public exhibition, any animal must be handled so there is minimal risk of harm to the animal and to the public, with sufficient distance and/or barriers between the animal and the general viewing public so as to assure the safety of animals and the public.

(2) Performing animals shall be allowed a rest period between performances at least equal to the time for one performance.

(3) Young or immature animals shall not be exposed to rough or excessive public handling or exhibited for periods of time which would be detrimental to their health or well-being.

(4) Drugs, such as tranquilizers, shall not be used to facilitate, allow, or provide for public handling of the animals.

(c)(1) Animals shall be exhibited only for periods of time and under conditions consistent with their good health and well-being.

(2) A responsible, knowledgeable, and readily identifiable employee or attendant must be present at all times during periods of public contact.

(3) During public exhibition, dangerous animals such as lions, tigers, wolves, bears, or elephants must be under the direct control and supervision of a knowledgeable and experienced animal handler.

(4) If public feeding of animals is allowed, the food must be provided by the animal facility and shall be appropriate to the type of animal and its nutritional needs and diet.

§ 2.132 Procurement of random source dogs and cats, dealers.

(a) A class "B" dealer may obtain live random source dogs and cats only from:

(1) Other dealers who are licensed under the Act and in accordance with the regulations in part 2;

(2) State, county, or city owned and operated animal pounds or shelters; and

(3) A legal entity organized and operated under the laws of the State in which it is located as an animal pound or shelter, such as a humane shelter or contract pound.

(b) A class "B" dealer shall not obtain live random source dogs and cats from individuals who have not bred and raised the dogs and cats on their own premises.

(c) Live nonrandom source dogs and cats may be obtained from persons who have bred and raised the dogs and cats on their own premises, such as hobby breeders.

(d) No person shall obtain live random source dogs or cats by use of false pretenses, misrepresentation, or deception.

(e) Any dealer, exhibitor, research facility, carrier, or intermediate handler who also operates a private or contract animal pound or shelter shall comply with the following:

(1) The animal pound or shelter shall be located on premises that are physically separated from the licensed or registered facility. The animal housing facility of the pound or shelter shall not be adjacent to the licensed or registered facility.

(2) Accurate and complete records shall be separately maintained by the licensee or registrant and by the pound or shelter. The records shall be in accordance with §§ 2.75 and 2.76, unless the animals are lost or stray. If the animals are lost or stray, the pound or shelter records shall provide:

(i) An accurate description of the animal;

(ii) How, where, from whom, and when the dog or cat was obtained;

(iii) How long the dog or cat was held by the pound or shelter before being transferred to the dealer; and

(iv) The date the dog or cat was transferred to the dealer.

(3) Any dealer who obtains or acquires a live random source dog or cat from a private or contract pound or

shelter, including a pound or shelter he or she operates, shall hold the dog or cat for a period of at least 10 full days, not including the day of acquisition, excluding time in transit, after acquiring the animal, and otherwise in accordance with § 2.101.

PART 3—STANDARDS

1. The authority citation for part 3 is revised to read as follows:

Authority: 7 U.S.C. 2131–2156; 7 CFR 2.17, 2.51, and 371.2(d).

§ 3.10 [Removed and Reserved]

2. Subpart A is amended by removing and reserving § 3.10.

§ 3.34 [Removed and Reserved]

3. Subpart B is amended by removing and reserving § 3.34.

§ 3.59 [Removed and Reserved]

4. Subpart C is amended by removing and reserving § 3.59.

§ 3.84 [Removed and Reserved]

5. Subpart D is amended by removing and reserving § 3.84.

§ 3.110 [Amended]

6. Subpart E, § 3.110, paragraphs (a) through (c) are removed, and paragraphs (d) through (g) are redesignated respectively as paragraphs (a) through (d).

§ 3.111 [Removed and Reserved]

7. Subpart E is amended by removing and reserving § 3.111.

§§ 3.134 and 3.135 [Removed and Reserved]

8. Subpart F is amended by removing and reserving §§ 3.134 and 3.135.

Done in Washington, DC, this 25th day of August 1989.

A. Strating,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 89–20424 Filed 8–30–89; 8:45 am]

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